Partnerships for vaccine development: building capacity to strengthen developing country health and innovation

Rebecca Hanlin

Doctor of Philosophy
University of Edinburgh
2008

Declaration

I declare that the content of this thesis is all my own work.

Rebecca Hanlin
May 2008

Abstract

Product Development Public-Private Partnerships (PDPs) are mechanisms used to incentivise health innovation for neglected diseases. PDPs undertaking clinical trial research in developing countries work – collaborate – at the interface of innovation and healthcare activities. Within the literature around innovation systems collaborative activity is deemed to build important organisational processes creating stronger institutions and enabling environments by increasing knowledge exchange. This process capacity building activity is recognised as important in some areas of the international development arena within which health related PDPs work. Using qualitative research methods this thesis studies the International AIDS Vaccine Initiative (IAVI) in Kenya to consider how partnership collaborative activity occurs, the interaction created between healthcare and innovation and, what capacity building results. This is an interdisciplinary study that mixes innovation systems thinking with an ethnographic/ anthropological rationale.

The Kenyan IAVI partnership takes multiple forms. It is an 'effective' partnership acknowledging benefits gained within unequal power relations making it impossible to also be a 'true' partnership. The partnership has characteristics of an innovation system because actors are conduits of knowledge. Collaborative activity creates knowledge exchange producing 'process capacity'. This less tangible, knowledge based, and organisational related capacity takes place within the partnership but is not overtly recognised as important. Focusing on process capacity highlights the linkages between innovation and healthcare activities. It also highlights the importance of considering AIDS vaccine research activities in a holistic, systemic manner. Understanding the partnership requires recognition of activities and multiple relations across time and space. The Kenyan IAVI partnership is not simply the result of international (macro) level discourse and storylines regarding the need to incentivise product development. Recognising this complexity moves beyond value laden notions of partnership towards understanding what is required to strengthen developing country health and innovation.

Acknowledgements

This study would not have been successful without the time and support given by everyone in Kenya involved in the IAVI research. I would like to give particular thanks to everyone at IAVI (Nairobi and New York), KAVI and KEMRI-CGMRC. I would like to also thank everyone I interviewed in Kenya for making the study possible. Asante sana kwa mawazo na majibu yako na kwa misaada yako yote.

Behind the scenes in Kenya, I need to acknowledge the logistical support of the ACTS and Cosmo, Kit, Sansi, and Tammi for their hospitality and friendship. Special thanks go to the late Anu Shah whose kulfi will never be forgotten.

Furthermore, I would like to thank James Smith, Ian Harper and Joanna Chataway for their supervision support. I need to also thank colleagues at Innogen for logistical and intellectual support. My student colleagues in Edinburgh and Wednesday morning coffee have made the PhD process painless. Recognition is also necessary of the ESRC funding for this PhD.

Finally, I would not have gotten where I am today without the support and guidance of a number of people close to me. I do not know how far back my thanks should go as many people and events have influenced my lifecourse. I am where I am today as a result of influences in my past as much as my present. The list starts with my parents for giving me the opportunity to see life differently. It includes a family friend, Ann, for giving me the idea of travel, my sister, Kate, for putting up with my rants and, Clare for providing glasses of wine.

Last but definitely not least, my husband Chris' unwavering support and encouragement deserves more than thanks.

Contents

List of tables and boxes

Abbreviations

ARV	Anti-retroviral therapy
CAB	Community Advisory Board
CCRC	Comprehensive Care and Research Centre
CDC	US Center for Disease Control
CEO	Chief Executive Officer
COO	Chief Operating Officer
CoP	Community of Practice
CRF	Case Report Form
CRP	Country and Regional Programs
CVI	Children's Vaccine Initiative
DNDi	Drugs for Neglected Diseases initiative
FHI	Family Health International
GAVI	Global Alliance for Vaccines and Immunization
GCLP	Good Clinical Laboratory Practice
GCP	Good Clinical Practice
GDP	Gross Domestic Product
HIV/AIDS	Human Immunodeficiency Virus/ Acquired Immunodeficiency Syndrome
IAVI	International AIDS Vaccine Initiative
KANCO	Kenya AIDS NGOs Coalition
KAVI	Kenya AIDS Vaccine Initiative
KDH	Kilifi District Hospital
KEMRI	Kenya Medical Research Institutes
KEMRI-CGMRC	KEMRI's Centre for Geographic Medical Research – Coast
KNH	Kenyatta National Hospital
LIMS	Laboratory Inventory Management System
M&E	Monitoring and Evaluation
MDGs	Millennium Development Goals
MMV	Medicines for Malaria Venture
MRC	Medical Research Council
MSM	Men who have Sex with Men
NACC	National AIDS Control Council
NFP	Not-For-Profit
NGO	Non-Governmental Organisation
NIH	National Institutes of Health
PDP	Product Development PPP
PEPFAR	US President's Emergency Fund for AIDS Relief

PI	Principal Investigator
PPP	Public – Private Partnership
R&D	Research and Development
SAAVI	South African AIDS Vaccine Development
SOP	Standard Operating Procedure
STS	Science and Technology Studies
TB	Tuberculosis
TRIPS	Trade Related Aspects of Intellectual Property Rights
UN	United Nations
UNDP	United Nations Development Programme
USA	United States of America
UW	University of Washington
VCT	Voluntary Counselling and Testing
VDP	Vaccine Development Partnership
WHO	World Health Organisation

Chapter One

Introduction

"On my first day at the International AIDS Vaccine Initiative (IAVI) project at the Kenya Medical Research Institute's (KEMRI) centre in Kilifi, a coastal town just outside of Mombasa, I was taken on a tour of the premises by the IAVI Project Manager. We started at his office in a new concrete and tin roofed set of buildings making up the Community HIV Centre. The Centre had been opened in March 2006, only a few months before my visit, to provide voluntary counselling and testing (VCT) facilities for the local community, a valuable service for the local community being one of the few VCT centres in Kilifi. What makes the Centre different to other VCT services is that when clients attend for VCT they are also asked if they would like to become involved in AIDS vaccine clinical trials and related studies should they fit trial criteria. As such the Centre provides the pool of volunteers, or what is known as the 'cohort', for IAVI's AIDS vaccine research trials.

Having been shown around the various rooms that make up the VCT centre and being introduced to staff there, we walked across the road and into the KEMRI main building. This is a modern building that would not look out of place in the UK or the USA; a mass of steel, glass and white concrete containing modern scientific research equipment and a library full of books. It was totally not what I was expecting as it is at odds with the typical picture usually given of African research institutes and a picture that fits with examples of other research sites I had visited. A number of research sites and laboratories I have visited have been housed in less modern, grand or well equipped surroundings. They tended to be housed in old concrete square box type buildings often without glass in the windows and lacking even the most basic of laboratory equipment such as microscopes. I was told the new building was funded by the Wellcome Trust who had a long standing collaboration with KEMRI in the area of malaria research. We moved through the KEMRI building following a covered walkway down the hill and through a doorway in the security wall that took us directly onto the premises of Kilifi District Hospital.

As we went through the gate in the wall we appeared to enter a different world. Far from the order, manicured gardens and serenity of the research centre we entered the hustle and bustle of an African hospital. Grass stood taller on the side of the path as we moved towards a mass of low rise concrete and tin roofed buildings making up different wards and hospital departments. As we came to the first set of buildings and rounded a corner we started moving through a steady stream of people: patients, doctors, nurses, orderlies and visitors all going about their business. We stopped in a square, partially covered by the corrugated tin overhanging roofs of the surrounding hospital wards and clinic. Row upon row of benches filled the square covered by further free standing tin roofs. On the benches sat mothers, small children strapped with brightly coloured kanga material to their backs, and old men holding on to their

walking sticks to steady themselves, while young men clustered in groups talking loudly. The IAVI Project Manager pointed to a nearby door labelled the Chest and Tuberculosis (TB) room and said, "This is where it all started".

He told me how when he first arrived in Kilifi there were virtually no VCT services available. There was one room set aside just down from the Chest and TB room to provide VCT but because of staffing issues it was nearly always locked (and when we tried the door it was locked on this occasion too). In order to improve the service a small group of staff started to offer services from a desk around the corner from the allocated VCT room and soon had 400 patients on the database who had attended for VCT. They eventually were able to move into and share the Chest and TB room as the TB clinic operated only on Fridays. The 'clinic' quickly began to outlive even this space and so proposals were put together to set up the "Comprehensive Care and Research Centre" at the hospital as it coincided with the set up of AIDS vaccine feasibility clinical trial research activities by IAVI in collaboration with KEMRI. He took me over to the new Centre – just a few metres away in a large new concrete and tin roofed building, complete with a shiny new plaque on the wall to mark its official opening on 28 March 2006. This Centre provides services, including anti-retroviral treatment (ARVs) provision, for adults who test positive for HIV/AIDS at one of the VCT centres in the town or the Community HIV Centre within the KEMRI compound and for children who test positive within the paediatric ward of the hospital. This centre, one of only a few placed in the town to provide ARVs, benefits from its inclusion in the IAVI project's clinical trial research activities as it means more trained staff to see patients and an improved supply of ARVs."

The above is a general account of part of my first day in Kilifi during my field work for this PhD thesis and highlights two main issues that are starting points for this thesis. I will discuss these two starting points below before introducing my thesis case study, the International AIDS Vaccine Initiative (IAVI). The first starting point is the linkage between innovation and healthcare activities. The second starting point is the nature of collaboration as a result of the rise of health product development public-private partnerships (PPPs). From these starting points three issues are raised which are the three main themes of this thesis. I will describe these themes and how in discussing them a number of research questions are raised which I answer in the remaining chapters of this thesis. The final section of this chapter outlines how I intend to answer these questions by giving an overview of the contents of the remaining chapters of this thesis.

1.1 Starting points

The opening account above highlights two starting points from which my thesis has developed. One of these issues, and one that leaps out at me when I read over my account, is the interconnectedness and yet separation of scientific research activities and healthcare provision. The relationship between, on the one hand, the scientific research (what will often be referred to in this thesis as 'health innovation' activities)[1] that occurs in the IAVI project at the Kenya Medical Research Institute (KEMRI) and, on the other, healthcare provision, is the ***first of two starting points*** for this thesis. KEMRI is Kenya's major scientific research establishment with a number of different research centres throughout the country. KEMRI conducts health innovation activities and does not conduct healthcare provision. It is the role of the Kilifi District Hospital to conduct healthcare provision. The KEMRI Kilifi centre, or KEMRI-CGMRC as it is known (KEMRI's Centre for Geographic Medical Research-Coast), has traditionally conducted mostly malaria research prior to its collaboration with IAVI on AIDS vaccine research. However, despite its physical separation (by a wall) from the District Hospital, KEMRI-CGMRC has to integrate its scientific research activities with routine healthcare activities in order for it to conduct its research successfully. This provides a cohort for trial research but at the same time also ensures trial volunteers receive Antiretroviral (ARV) treatment opportunities in line with the ethical requirements of clinical trial procedures. This, as I shall discuss below, is at odds with much policy and practice that has often discussed these issues of health innovation and health care provision separately and discretely. This account highlights how much the care activities have benefited from this interrelationship by providing more resources and facilities. However, as this thesis in Chapter Five will highlight, there are also benefits for the research of this interconnectedness by ensuring more streamlined processes of recruitment of research participants as well as providing avenues for care referral to these participants.

[1] Health innovation in this thesis refers to the research and development (R&D) process to produce a new medicine (drug, vaccine or diagnostic). A full explanation of this definition is given in Section 2.3 of Chapter Two.

The ***second starting point*** for the thesis, the nature of collaboration, is also highlighted by the above account, particularly as a result of the absence of the discussion of the nature of the collaboration activities in the account. The account explains that IAVI is working with KEMRI-CGMRC and that the Wellcome Trust also works with KEMRI-CGMRC. However, it does not go into detail as to how these relationships work despite having been the focus of my research. The account does however highlight that the District Hospital's services and the wider community benefited from the collaboration with IAVI as it provided a new building and new HIV/AIDS care services that were not available before. As such, this account highlights the difficulty of discussing collaboration when it is so easily dwarfed by issues of ensuring care provision and reducing the disease burden caused by HIV/AIDS. My account highlights how I was struck on arriving in the middle of the hospital firstly by the stark physical differences between the research and care settings and, secondly, by the human face of illness. The result was that the focus of my account of the visit became less about how the collaboration took place (despite being the focus of my fieldwork) and more about these other more immediate issues that were so visible during my visit. When the effects of disease and the difficulties of delivering healthcare are so striking the focus inevitably becomes 'what is needed to end this crisis?' or 'how can we help?' and 'what are the medicines (drugs, vaccines or diagnostics) that they need?' Such an approach, I will argue in this thesis, is common when focusing on the role of health innovation activities. The emphasis of health innovation activities becomes the end point; it is on the need to find solutions that will treat, cure or stop the spread of HIV/AIDS. The process it takes to get there and how it plays out of the ground is less often focused upon.

Thus, it is this little analysed collaborative process that this thesis has as its second starting point. In particular I am interested in understanding the workings of collaborative product development PPPs as exemplified by the IAVI partnership. These product development PPPs have been promoted as a means of, what is termed, 'incentivising' or encouraging development of the medicines needed for diseases predominately affecting developing country populations, such as HIV/AIDS, which have received little research investment by private pharmaceutical companies in the

past. However, as I shall discuss below, despite recognition of the difficulty of ensuring 'true' and 'equal' collaboration there have been few studies that have looked at the way these partnerships actually function on the ground in the developing countries in which they increasingly work. Secondly, as the main chapters of this thesis highlight, an emphasis on the end point increases the opportunity for a distorted view through which one sees these partnerships making it difficult to be critical of them. For example, when mothers with children are dying from AIDS due to the lack of a vaccine all too often attention is placed, understandably, on the vaccine itself rather than the collaborative activities that are needed to ensure the vaccine is developed and delivered. This situation is exacerbated because there are currently few alternatives to these partnerships. In turn the lack of other mechanisms to conduct such health innovation activities makes it difficult to focus on an alterative to these partnerships. The result is a predominantly uncritical view of these partnerships which reflects a wider debate around the role of 'development' and scientific research capacity building activities such as that undertaken by product development PPPs like IAVI.

The two starting points for my PhD developed out of an earlier MSc dissertation I undertook. In researching and writing my MSc dissertation in 2004-2005, I found that the specifics of the institutional partnership process of global health PPPs in developing countries does not receive much attention in the literature discussing health product development PPPs such as IAVI. The focus is often concerned with what is required for the achievement of the end point – on working towards the development of a vaccine. However, I came to realise in researching from an innovation systems perspective for my MSc dissertation,[2] the South African AIDS Vaccine Initiative (SAAVI), a country level product development PPP, that innovation is much more than simply the production of end-points. Equally important in its own right is the process taken to ensure the successful production of drugs, vaccines or diagnostics.

[2] And since published as Hanlin (2006) and Hanlin (2007)

I came to these conclusions following my aim in my MSc dissertation to consider how and what 'value added' or benefit gained from taking part was created for those involved in the SAAVI partnership. In my MSc dissertation I was interested in looking at whether there has been a change in the way 'value added' is created based on the argument that:

> "…we may be moving from a post-industrial to a post-knowledge age in which human relations, values and means as ends are critically assessed giving new meaning to "value added"." (Healy, 2001: 8)

To me this quote seemed to sum up what was happening in the wider environment that explained the rise of partnerships. In my MSc dissertation I studied this to see what impact it had on success. I considered the reasons that health product development partnerships succeed in ways that went beyond the dominant economic argument of market failure that is usually put forward (see Section 2.1). In order to do this and building on the idea that successful innovation requires strong linkages or collaboration in the form of an 'innovation system' from within the field of innovation studies (c.f. Edquist, 1997; Freeman, 1987; Lundvall, 1995), in my MSc dissertation, I asked whether more intangible forms of 'value added' such as collaboration were important for those involved to ensure that success was achieved (measured in terms of being able to conduct activities that lead towards the development of an affordable and effective AIDS vaccine). I concluded that collaboration was important because it built forms of 'process capacity' or less tangible, knowledge based types of capacity that go beyond simply training staff or provision of infrastructure support. Forms of process capacity relate to the type and strength of networked ties between a wider range of different actors who need to be involved for successful AIDS vaccine development research to take place. In particular, my MSc dissertation highlighted that often there were important networked relations occurring between those involved in the traditionally separate fields of innovation and healthcare.

In my PhD thesis I move on from these conclusions and look in more depth specifically at the value added created by collaboration within these product development partnerships and in particular the type of capacity building activities

that take place. In order to do this, my PhD research looks at one of the oldest and largest health product development partnerships, the International AIDS Vaccine Initiative (IAVI), to consider how collaboration takes place within the partnership, whether it leads to an interaction between those involved in innovation and those involved in healthcare activities and whether this occurs as a result of specific knowledge based forms of capacity building which I term 'process capacity'.

The SAAVI study as I have mentioned above, highlighted the linkage between innovation and health as a result of process capacity activities. In thinking about my PhD research at the start I wanted my research to be a further attempt to mould these two different perspectives of health and innovation together. I also realised I was in a unique position to be able to do this having a health policy background but having recently become involved in the study of innovation.

I became involved in these two areas working with, and later researching, PPPs in Tanzania and Nigeria around insecticide treated bednets for malaria prevention from a health policy perspective. At the time, I did not realise that I was also actually working with and researching health product innovation networks on the ground. My first thesis on the topic was written from the standpoint of health policy analysis – looking at actors, process, contents and policy (Walt, 1995) using stakeholder analysis (Freeman, 1984). Following this, I applied for a PhD researching PPPs in AIDS vaccine development assuming I would research them from a similar standpoint as I had in the past. However, when I studied for an MSc in Science and Technology Studies (STS) and met people in innovation studies I saw it was possible to mould the two frameworks together as others were starting to do but also to going further in this regard. I wanted to start from the standpoint of health policy rather than innovation to integrate ideas of health innovation and health research with discussions of health systems and care provision. I wanted to acknowledge my background in health economics taking as a starting point work on pharmaceutical economics within the health policy field around neglected disease product development and combine it with work from STS on pharmaceutical innovation and the growing literature on health innovation and research. Such thoughts resulted in

the creation of my final research questions around the linkages between innovation and health within the IAVI partnership, its work and also have provided an opportunity to reflect on the issues this raises for consideration at a wider policy level.

In choosing a product development PPP to research for this study I decided to keep with the theme of AIDS vaccine research and look at the partnership, IAVI, that has been established for the longest period of time (both in terms of AIDS vaccine research and health product development partnerships more generally) and as such is often used as an example of health product development PPPs and yet has received little independent analysis. In this sense IAVI has "strategic importance in relation to the general problem" (Flyvberg, 2001). Practically, this choice of case study was also assisted by my research centre's existing access to IAVI, having conducted other research around IAVI just before I started my PhD. Keeping with the theme of AIDS vaccine research was also useful as I did not have to learn new science and also had a good understanding of the main actors involved in this research as a result of my research for my MSc. I will now provide an overview of IAVI.

1.2 The International AIDS Vaccine Initiative (IAVI)[3]

IAVI, the case study of my PhD, was set up in 1996 as a not-for-profit (NFP) organisation based out of New York with the aim of promoting the development of an effective and affordable AIDS vaccine. A full timeline of IAVI's activities and developments has recently been published in its 10-year history (IAVI, 2006) and is provided in Appendix 1. I will now give a brief overview of its activities and their changes over time before providing an introduction to IAVI's organisational structure and how it works on the ground in Kenya.

[3] The content of this section was informed by discussions with interviewees from IAVI and its partner organisations and the reading of IAVI (2006) and Berkley (2006)

1.2.1 IAVI's activities

Seth Berkley, its founder and Chief Executive Officer (CEO), emphasises the organisation's comparative advantages of "speed, flexibility, and the ability to take informed risk" describing it as a 'new kind of PPP' with a 'vaccine industry product management model' (Berkley, 2006:53-66). The emphasis here is on the private 'P' in PPP. The focus is placed on the efficiencies that a private sector pharmaceutical vaccine industry model following a product portfolio and pipeline industry model (a number of different candidate vaccines at different stages of development) can bring to the public need for an AIDS vaccine. However, IAVI did not start out working in similar ways to a pharmaceutical company. It was set up as a NFP advocacy organisation to promote the development of an effective and affordable AIDS vaccine. In the last 10 years IAVI's activities have diversified and changed. It now has a number of different activities and objectives that it focuses on other than simply its advocacy activities. When I spoke to IAVI's Chief Operating Officer (COO) in mid 2007, he described IAVI as having four main areas of activity, which he likened to the leg of a table and each of which were needed to keep upright the top of the table or AIDS vaccine development activities as a whole:

- Advocacy and global communications;
- Research and Development (R&D);
- Public policy and;
- Working in the developing world/ partnership

IAVI started life involved only in trying to promote the development of an AIDS vaccine by scientists external to IAVI, working as an advocacy orientated NFP. This work is still an important focus of its activities and is combined with a strong focus on communications. Its advocacy activities include IAVI staff involvement in discussions regarding the priorities of science budgets and general funding requirements for AIDS vaccine development, the international access to medicines (drugs, vaccines and diagnostics) debate, and generally publicising what is needed in order for an AIDS vaccine to be developed. This work is aided by the efforts of a policy team who commission and conduct research into these areas and develop policy documents based on these findings that are then used in the lobbying and

advocacy process. IAVI's activities in the area of advocacy in 2006 included supporting South-South collaboration on vaccines by providing technical input to the first India-Brazil-South Africa Heads of Government Summit and holding meetings with the Indian and Rwandan Presidents as well as senior leaders of China to retain political support for AIDS vaccine research in these developing countries. Advocacy activities also take place through working with local communities and relevant stakeholders (from the media to health professionals) in developing countries where such research takes place to provide information about AIDS vaccine research. IAVI also conducts activities in the area of mobilising financial support for continued R&D efforts through working with the HIV Vaccine and Microbicides Resource Tracking Working Group. It also engages in discussions, develops policy briefs and supports independent research regarding the best way to conduct neglected disease product development more generally with other stakeholders. In the area of HIV/AIDS this work increasingly takes place through the activities of the Global HIV Vaccine Enterprise, an alliance of organisations from around the world with the aim of accelerating global HIV/AIDS vaccine development activities.

In 1998 IAVI published its first *Scientific Blueprint for AIDS Vaccine Development* outlining what it considers were the gaps in the scientific research requirements in AIDS vaccine development and where it would get involved in the process through the development of Vaccine Development Partnerships (VDPs). This report signifies the first turning point in IAVI's evolution towards the organisation it is today. It has continued its advocacy activities but since 1998 has become more involved in the actual scientific and research process of vaccine development itself. Since the late 1990s IAVI's senior staff felt it was necessary to not only get involved in promoting and financing AIDS vaccine innovation efforts but also to develop its own R&D department to ensure scientific questions currently neglected by others were being investigated. The R&D department when initially set up oversaw the development of a number of VDPs. These partnerships were initially designed to bring together researchers from the developing and developed world. Through these partnerships various stakeholders collaborate with IAVI to move forward aspects of AIDS vaccine research particularly to facilitate the conduct of clinical trials around

potential vaccine candidates. It has adopted a pipeline and portfolio approach to its R&D activities, similar to that of a pharmaceutical company. This means it oversees the development of various vaccine candidates (its portfolio) at different stages of the vaccine development (the pipeline) process. IAVI has concentrated on applied research and clinical development activities (the production of a vaccine and its clinical testing). IAVI has six vaccine candidates in its portfolio that have been tested in 11 human trials.[4] IAVI's activities in the area of applied research have increased since 2005 with the creation of its own dedicated AIDS Vaccine Development Laboratory but also as a result of other scientific collaborations (it calls them 'consortiums') that bring together scientists to brainstorm and work on promising but neglected areas of research. The R&D department has staff members who also work in IAVI's regional offices around the world.

Since 2003 IAVI has opened regional offices in India, Kenya and South Africa to support the work that is conducted in developing countries and the need to support advocacy and policy work in these areas too. Since starting to conduct trials in developing countries in 1998, IAVI has increasingly become involved in working in the developing world. IAVI currently (as of October 2007) has six vaccine trials ongoing out of a total of 18 HIV/AIDS vaccine clinical trials being conducted around the world. Only one of these is taking place in Kenya. However, other feasibility and clinical research studies (all of which are forms of clinical trials) are being undertaken at the two research institution partners' sites in Kenya. A breakdown of the studies and trials that were taking place in Kenya when I undertook my fieldwork in 2006 are outlined in Figure 1.1. These activities are coordinated in New York by the Country and Regional Programmes (CRP) department which was set up in 2003 (with dedicated staff in the regional offices) "to create a stronger, structured, and responsive presence… while fostering broad-based advocacy and ensuring high quality to meet global standards of research" (IAVI, 2006: 12). The CRP is in charge of the day-to-day running of the regional offices.

[4] As per an IAVI factsheet (http://www.iavi.org/file.cfm?fid=40901) accessed on 24th October 2007

1.2.2 The organisation of IAVI

IAVI is headed by Seth Berkley as CEO and is managed from the Executive Office consisting of the CEO and the COO out of the head office in New York. Day-to-day programmatic activities are undertaken within the New York head quarters, the three regional offices (East Africa, India and South Africa) and an office in Amsterdam that coordinates its European activities (particularly relations with European donors) with all activities managed from the Executive Office. IAVI's scientific direction is overseen by a Scientific Advisory Committee made up of 13 scientists from around the world with expertise in AIDS vaccine development. There is also a 14 person Policy Committee that assists in setting direction of IAVI's policy department. An outline of IAVI's organisation, as I have come to understand it, is provided in Appendix 2.[5]

The name 'IAVI' is often used to refer to both the physical organisation of the NFP in New York and its regional offices as well as the overarching global networked entity created as a result of its collaborations with partners in 23 countries around the world.[6] It is this latter organisational set up that gives it the definition as a PPP. Its partners include:

- Private pharmaceutical and biotechnology companies such as Crucell and GlaxoSmithKline
- Public sector research organisations such as the US National Institutes of Health
- Philanthropic organisations such as the Bill and Melinda Gates Foundation
- Bi-lateral donors such as the UK's Department for International Development
- Non-governmental organisations (NGOs) and civil society groups

IAVI's activities take place in two arenas. First, are those at a global level through the collaborations it has with its partners around the world. Secondly, there are its

[5] IAVI's official organogram is not publicly available and therefore I have pieced together my own version based on the discussions I have had and the documents I have accessed.
[6] For the rest of this thesis I will refer to the not-for-profit organisation in New York and its regional offices as 'IAVI' and the wider partnership as 'the IAVI partnership'

activities in individual countries. These include its activities in the US but also those that occur in developing countries which are predominately managed through its regional offices[7] that revolve around clinical trial research.

It is this latter arrangement which is the subject of study in this thesis. I am interested in how IAVI, the not-for-profit organisation, relates to Kenyan public sector research organisations that conduct clinical research for IAVI – specifically the Kenya AIDS Vaccine Initiative (KAVI) within the University of Nairobi and the Centre for Geographic Medicine Research-Coast (CGMRC) of the Kenya Medical Research Institute (KEMRI) – together with Kenyan government departments, civil society and NGOs.

1.2.3 IAVI's activities in Kenya

IAVI's first involvement with Kenyan institutions was as the funding partner in the first of its VDPs in 1998 with the newly initiated KAVI and the UK's Medical Research Council (MRC) which aimed to develop the first vaccine candidate for an African Clade or sub-type of HIV. Learning from difficulties over intellectual property arrangements as well as the negative press that followed, IAVI re-negotiated its VDP agreement in 1999. The new agreement was between the University of Nairobi, the University of Oxford and the UK's MRC. The new partnership provided an opportunity for the first African vaccine trial of a candidate vaccine for an African Clade of HIV to take place. This trial started in 2001 in Kenya. Although not a success (the trial was halted in 2004 after Phase II tests to measure safety and immunogenicity to find the best dose and regime failed), organisational and management lessons were learnt as a result of the VDP and the trial activities. IAVI realised the need for a more regional presence in the area and, as already mentioned, opened a regional office in Nairobi to serve its East and Southern Africa activities in 2003. The trial also validated the strength and usefulness of Kenyan clinical research sites and in 2003 IAVI increased the number

[7] I use the word 'predominately' here because, as Chapter Four points out, the regional office in East Africa is not always the nodal point through which all information is passed.

of sites, including in Kenya, that it would resource and train up for vaccine trial activities.

IAVI now has two VDPs with groups in Kenya: KAVI and KEMRI-CGMRC. Between these groups there are four supported trial sites which conduct a range of feasibility and operational research as well as actually conducting clinical trials of vaccine candidates. An outline of these sites and their activities is given in Chapter Four. An overview of the research that has been conducted at these sites with IAVI support in 2006 when I was conducting my fieldwork is outlined in Figure 1.1.

Each of these sites has a different institutional history and this is somewhat pertinent to understanding their differing relationships with IAVI. KAVI is an institute housed within the Department of Microbiology at the University of Nairobi based within the grounds of Kenyatta National Hospital in Nairobi. It came into being in the late 1990s following the decision to fund clinical trials of the first AIDS vaccine candidate in collaboration with the UK's MRC and IAVI funding as outlined above. KAVI's history is therefore inextricably linked to that of IAVI's and this is telling in terms of the way the partnership is perceived by long standing members of IAVI in Chapter Four. KEMRI-CGMRC on the other hand, is a centre within KEMRI, the country's national institute for health research which was founded with government backing in 1979. The CGMRC is based in Kilifi and has long standing links with the UK's Wellcome Trust as well as other foreign research groups which have provided funding for various research projects supplementary to the government funding of its administration and staffing costs. Thus IAVI's relationship with KEMRI-CGMRC is, on paper at least, no different from that which it has with the Wellcome Trust for example.

The relationship between KAVI/ KEMRI-CGMRC and IAVI is managed by a contract. IAVI's contract with KAVI is discussed in Chapter Four and basically provides full funding of KAVI (the fixed and project costs) over a five-year period. IAVI's contract with KEMRI-CGMRC only provides financial support for project related costs, however this has included financial support for the provision of new infrastructure (buildings and lab equipment) and full project staffing costs. These

contractual relationships differ from IAVI's relationship with other actors involved in AIDS vaccine development related activities such as Government of Kenya ministries, community or advocacy groups, and other research organisations in the country where no such contract binds them together.

These differing institutional histories and IAVI's relationship with each group also affects the attitude to staffing within KAVI and KEMRI-CGMRC. KEMRI has long had foreign staff attached to its projects. When you walk around the Kilifi offices you hear many non-Kenyan voices of the expatriate staff working there. Similarly the KEMRI-CGMRC IAVI project is headed up by an expatriate manager who is assisted by an expatriate deputy. There is one other expatriate on the project staff, a social scientist. This is not the case at KAVI where all permanent project staff have been Kenyans. However, for the initial years of KAVI, IAVI provided one full-time project consultant (an expatriate) to support activities within KAVI and who was based full-time at the KAVI offices until 2003. KAVI also was provided with support from visiting consultants as and when needed.

The role of the regional office in Nairobi is to provide an immediate contact point for the clinical research sites when they need to get in touch with IAVI. At the same time the regional office in Nairobi has other functions. Firstly, it provides technical support to these sites and organises capacity building activities. An emphasis has been placed on building local capacity, particularly in terms of laboratory expertise, with sites being supported in gaining Good Clinical Laboratory Practice (GCLP) certification, technical support being provided by a Core Immunology Lab set up in London in 2001 and a specific data management system (LIMS) established in 2002. As I will discuss in Chapter Five this emphasis has changed over time and is heavily focused on traditional forms of capacity building through training and infrastructure support.

Research (end 2006)	Description	Research locations
Protocol B	A study of HIV incidence within high-risk cohorts	• KAVI - Kenyatta National Hospital • KAVI – Kangemi • KEMRI-CGMRC – Kilifi • KEMRI-CGMRC – Mtwapa
Protocol C	A study of acute HIV infection looking at recent infection (sero-conversions in Protocol B)	• KAVI - Kenyatta National Hospital • KAVI – Kangemi • KEMRI-CGMRC – Kilifi • KEMRI-CGMRC – Mtwapa
Protocol D	Study of normal values to find baseline laboratory and haematology criteria	• KAVI - Kenyatta National Hospital • KAVI – Kangemi • KEMRI-CGMRC – Kilifi
V001	A Phase I, Randomized, Placebo-Controlled, Double-Blind Trial to Evaluate the Safety and Immunogenicity of a Multiclade HIV-1 DNA Plasmid Vaccine Followed by Recombinant, Multiclade HIV-1 Adenoviral Vector Vaccine or the Multiclade HIV-1 Adenoviral Vector Vaccine Alone in Healthy Adult Volunteers not Infected with HIV	• KAVI - Kenyatta National Hospital • KAVI – Kangemi

Figure 1.1 Overview of IAVI AIDS vaccine research in Kenya[8]

1.3 From starting points to thesis themes and research questions

In studying the IAVI partnership in Kenya I examine in more detail three issues that can be seen as the main themes of my thesis and which develop out of the starting points mentioned above. The two starting points for this thesis introduced above relate to the relationship between innovation and healthcare and the nature of collaboration as a result of the rise of product development PPPs. As the starting points for this thesis, they are also two of the main themes that run throughout this thesis. There is also a third theme within this thesis, expressed less directly within

[8] Description taken from IAVI database of on-going trials (http://www.iavireport.org), details received from trial sites and Priddy (2007)

the account above, that develops out of the starting point of collaboration and the rise of product development PPPs. This third theme relates to scientific research capacity building. This theme, as I shall outline below, also helps to relate the nature of collaboration within product development partnerships to the linkage between innovation and health. The relationship between these starting points and the core thesis themes is graphically outlined in the top half of the thesis overview map (Figure 1.2). In considering the starting points and the consequential thesis themes that they produce, I developed a number of research questions. In the following sub-sections I will provide a brief introduction to each theme as an introduction to my research questions and discuss the main issues raised by answering these questions. The links from the starting points and themes to the research questions and resulting issues are graphically illustrated in the bottom half of the thesis overview map (Figure 1.2). These themes and the research questions (together with how my thesis adds to the health innovation and development literature) are discussed in detail in the thematic background in Chapter Two.

1.3.1 The rise of public-private partnerships (Theme 1)

Product development PPPs, or PDPs,[9] are seen as mechanisms to incentivise the production of drugs, vaccines and diagnostics (medicines) for diseases affecting the developing world, particularly 'neglected diseases' so defined because populations in many developing countries do not have the purchasing power to buy the medicines needed to prevent or cure these diseases (often argued as creating a market failure). These partnerships are seen as the correct mechanism needed because collaboration through partnership is seen as economically efficient reducing risks and costs to those involved. It is also seen as socially useful in an increasingly networked world. These arguments place a focus on the importance of the institutional relations within partnerships. Yet the discussions of these partnerships often focus on the incentivising role of the partnerships to produce new products (solving the market failure) at the expense of asking how the partnerships work. I look at how

[9] This is an increasingly common abbreviation for PPPs such as IAVI as it differentiates them from PPPs that concentrate on product access or health systems and policy issues being based on a classification system proposed by Buse and Walt (2000b). I will use this abbreviation to refer to product development PPPs for the remainder of this thesis unless otherwise stated.

collaboration occurs within one type of PDP, IAVI, and ask ***how does collaboration occur within this partnership?*** In so doing I get to grips with the power and politics of partnership to discuss the issues of who needs partnership and whether partnership activities have other functions than simply incentivising product development (linking it to questions in Themes 2 and 3).

1.3.2 The linkage between innovation and health (Theme 2)

Until recently issues of healthcare and issues of innovation (or scientific R&D to produce medicines) were not considered in the same academic or policy circles. This is despite the fact that, as my fieldwork account above highlights, these two activities are interlinked in the case of clinical trial research. In recent years researchers and practitioners in these two areas have started to interact but come with literatures, theories, arguments and policies from different starting points of economic development and social justice. In particular, the link between medicines as something other than an input to a healthcare system has not often been made within health policy circles. In the innovation field there is much more recognition of the feedback loops and interaction between the producers and users of products particularly in terms of the knowledge exchange between actors as a way of enhancing innovation. In recognition of this, I ask ***whether interaction takes place between those involved in innovation and those involved in health and what type of interactions these are?*** In asking these questions I look at the knowledge-based relationship between innovation and healthcare, the existence of which builds a form of what I term 'process capacity' or organisational level capacity (linking to questions within Theme 3).

1.3.3 Collaboration and capacity building (Theme 3)

The role of knowledge exchange is seen within the innovation field as strongly linked to the quality and effectiveness of collaborative activity. Promoting this is a form of capacity building. Capacity building is at the heart of scientific research collaborations between developed and developing countries, as exemplified by the IAVI partnership in Kenya. Discussions of what should be included in capacity

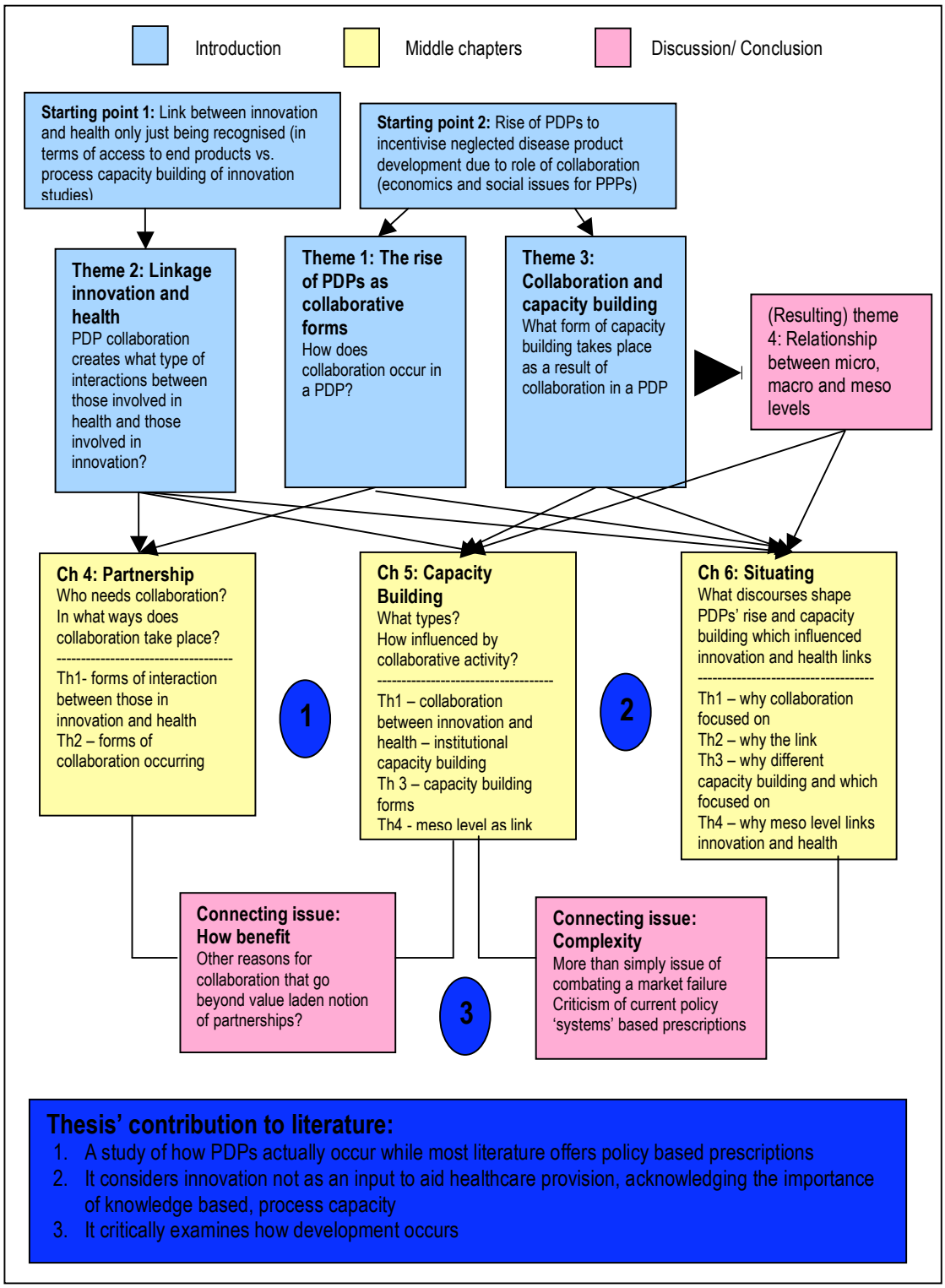
building activities have moved from focusing on individual skills training and infrastructure assistance towards focusing on what is required for sustainable, long term success. Increasingly an emphasis is being placed on the building up of knowledge management skills and enhancing less tangible organisational and process forms of capacity to strengthen institutions and build enabling environments. I therefore ask in relation to the IAVI partnership in Kenya ***what forms of capacity building take place as a result of partnership activity?*** In particular, I consider if organisational forms of capacity including those built around knowledge exchange and collaboration – through 'process capacity' – are important.

1.3.4 Further themes and issues

The role of organisational based process capacity emphases the role of the meso or institutional level as a link between actors within a partnership i.e. the importance of the partnership structure. This is one part of a fourth theme that has developed through the writing of the thesis relating to the relationship between different levels of influence (macro, micro and meso). The influence of the global (macro) and the local (micro) are raised when I consider how understanding the way partnerships such as the IAVI partnership in Kenya work and the form capacity building takes requires consideration of, not only the internal workings of the partnership (the local and micro), but also the wider external influences (the global and macro).

In discussing the three main themes there are two other connecting issues that are highlighted and which are discussed throughout the thesis. These are the issues of other forms of benefit from product development partnerships and linked to this the complexity of the field. Both issues raise further questions regarding the role of PDPs such as IAVI and how they are assessed. These questions are not specifically addressed within this thesis but are outlined in brief in the concluding chapter as areas of potential future research.

Figure 1.2 Thesis overview map: starting points, themes and major issues



1.4 Chapter overview

In order to address these various themes, research questions and issues my PhD has three main chapters. The first main chapter (Chapter Four) addresses the issue of partnership to discuss Theme 1 on the rise of PDPs. The second main chapter (Chapter Five) addresses Theme 3 by investigating the issue of capacity building and also Theme 2 regarding the linkage between innovation and health. The third main chapter (Chapter Six) addresses all three themes situating the findings from the earlier chapters within the wider discourse that explains, and influences, the three themes of the thesis. I shall now outline briefly the contents of each of these main chapters. A graphical representation of the linkages between my thesis themes and the chapters can be found in Figure 1.2 where the main themes are found in blue boxes and the main chapter outlines are found in the yellow boxes. The main connecting issues (pink boxes) that I observed in analysing my data I discuss in my conclusion chapter together with a possible fourth theme of the thesis that becomes evident as my thesis progresses. My thesis also contains a methodology chapter and a thematic background chapter which is found immediately after this chapter.

1.4.1 Chapter Two – Thematic background

Following on from the starting points outlined above, I outline in Chapter Two a discussion of these two starting points: the linkage between innovation and health and the rise of product development PPPs or PDPs. These become the first two themes that run through this thesis. I also explore a third related theme of scientific research capacity building. In discussing these themes I also discuss how I came to my research questions. During my discussion of these research questions in this chapter I also discuss the identification of gaps in the literatures of health policy, innovation and development studies.

1.4.2 Chapter Three – Methodology

In this chapter I outline details of my choice of research methodology, data collection and analysis techniques as well as certain study limitations. In particular, I highlight

how and why I have used a qualitative research methodology within what I term the 'spirit of ethnography' by outlining how I use the critical stance from within the anthropology and ethnography of international development to really understand what is happening within IAVI. I discuss how this thesis is strongly interdisciplinary in nature in terms of the methods that it uses and the different levels of focus that the study has. I outline my choice of data collection methods which principally used in-depth qualitative interviews and my data analysis technique which took place using a form of grounded theory approach whereby theoretical conclusions developed out of a reading of the data.

1.4.3 Chapter Four – Partnership

The main purpose of Chapter Four is to discuss the type of partnership that is found within the IAVI partnership at a country level in Kenya. In so doing, the chapter makes explicit the fact that the way the IAVI partnership is understood and operates differs depending on the level at which one studies the partnership activities. What can be termed 'the IAVI partnership' is structured in a very different way at a country level than it is when considered in terms of 'the IAVI partnership' as a whole on an international level. I show how at the country level in Kenya, what is termed an IAVI partnership is not one homogenous entity but involves a complex and at times unequal interplay between different actors. The partnership has characteristics of what are termed 'bottom-up' partnerships, 'top-down' partnerships and particularly 'parental' partnerships. In all these instances the interactions that take place do not occur only within the discrete confines of scientific research activities but also spill over into the healthcare provision sector. As such this chapter is predominately concerned with addressing the first overarching theme of this thesis on the rise of PDPs but also relates to the second thesis theme regarding the linkage between innovation and health. The chapter also discusses how the complexity of partnership can be better understood using an interdisciplinary perspective drawing on ideas from within the innovation systems and anthropology of development literatures.

1.4.4 Chapter Five – Capacity building

In this chapter I specifically address the third overarching theme of this thesis relating to the role of scientific research capacity building. This chapter provides an overview of the different types of capacity building opportunities that are available as a result of the linkages and networking relations that occur within what can be termed 'the IAVI partnership' in Kenya. In particular I outline how it is possible to see not just the creation of individual skill based capacity, in the form of training or the provision of infrastructure support, which traditionally has taken place in development assistance programmes and partnerships between a 'developed' partner with skills and resources and the 'undeveloped' partner. I stress the role and importance of what I term 'process capacity' or less tangible, knowledge based forms of capacity that occur as a result of linkages between a variety of different stakeholders involved in the partnership. This chapter highlights how capacity building activities can provide the linkage point for integration between those involved traditionally in scientific research activities (innovation) and those traditionally involved in healthcare provision. As such, the chapter also engages with the second overarching theme of this thesis regarding the linkage between innovation and health.

1.4.5 Chapter Six – Situating

This chapter discusses all three themes by moving beyond the partnership level to consider other issues that impact the way collaboration and capacity building take place. In this chapter I bring together the main conclusions of the previous two chapters on partnership and capacity building to discuss the discourses (ways of acting) that influence the rise of PDPs and capacity building activities but also explain the need to link innovation and health. In particular, this chapter highlights the complexity that surrounds IAVI as a partnership and therefore explains the complexity that is evident in the way it conducts its capacity building activities. I highlight how IAVI was created by, is made up of, and produces a variety of different operational level storylines (ways of explaining) situations. In making these conclusions my thesis engages with a wider argument around the role of international development assistance. In trying to move discussion forward in this

area, I outline the usefulness of considering the IAVI partnership as a complex assemblage of actors that coalesce around a specific issue (AIDS vaccine development). I conclude by arguing that taking a wider perspective like this provides an opportunity to move beyond value-laden notions of partnership and develop ways of understanding that provide a clearer picture of health innovation efforts within the IAVI partnership in Kenya.

1.4.6 Chapter Seven – Conclusion

This last chapter outlines the main findings of my thesis, recapping the answers to my research questions around the three thesis themes. It reviews the emergence of a fourth theme regarding the relationship between the macro, micro and meso levels. The chapter briefly discusses two connecting issues that have also emerged as the thesis has progressed. The first issue relates to how different groups benefit from being involved in collaboration within IAVI and raises the question of whether focusing on process forms of capacity building provide a means of moving beyond value-laden notions of partnership. The second issue relates to complexity and its evidence in numerous aspects of this discussion. It highlights how the issue of health innovation for neglected diseases cannot simply be seen in terms of overcoming just 'market failures' but also 'social failures' that relate to process capacity and the collaborative process. Acknowledging this complexity, I conclude in this chapter, is important in order to develop useful ways forward in the area of health innovation not only for AIDS vaccine development but also neglected disease product development more generally. These issues raise some areas of potential further research and these are also discussed in brief in this chapter.

Chapter Two

Thematic background:

A literature review and discussion

In Chapter One I outlined two starting points for this thesis: the linkage between innovation and health and the rise of product development PPPs. These set the scene and provide the catalyst for three themes that run throughout my thesis. The first two themes, as outlined in Figure 2.1, are directly related to the starting points. The first theme relates to the starting point regarding the rise of product development PPPs, or PDPs. The second theme relates to the starting point of the linkage between innovation and health. The third theme relates to scientific research capacity building and is a theme that integrates together the previous two. It does this when it takes into consideration 'process capacity' or less tangible organisational and knowledge based forms of skills and capabilities.

I will now discuss each of these themes reviewing the literature and issues raised. With each theme I will explain how the issues raised resulted in my choice of research questions and how by answering them I can contribute to various literatures based on gaps in the literatures which I identify in this chapter. In particular, I will discuss how this thesis provides important contributions to the study of PDPs and scientific research capacity within health policy as well as the value of the interdisciplinary use of concepts from within innovation systems thinking with certain aspects of the anthropology of development.

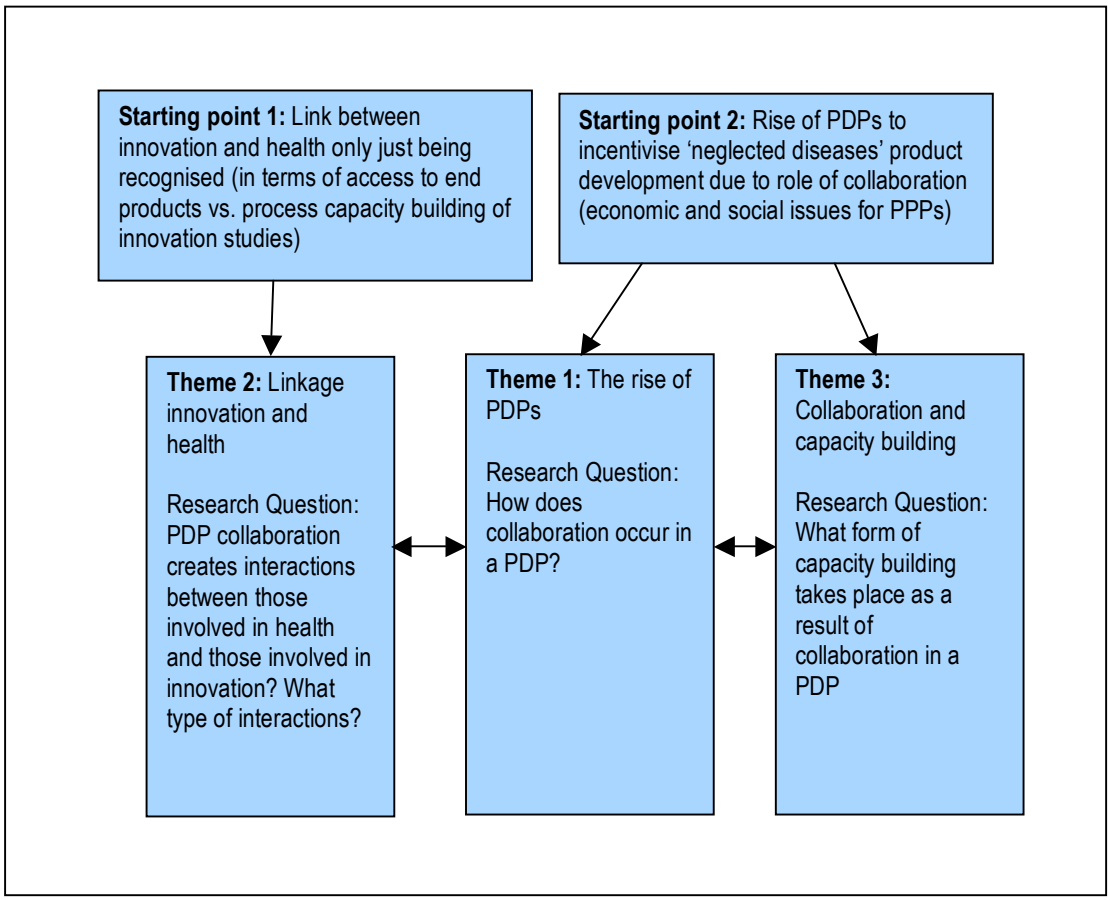


Figure 2.1 Thesis starting points and themes

2.1 Theme 1 – The rise of Product Development PPPs as collaborative forms

The PDP has been put forward as a mechanism to incentivise the development of medicines (drugs, vaccines and diagnostics) for HIV/AIDS affecting the developing world. Calls for more incentives to promote product innovation for AIDS vaccines are understandable as the toll of HIV/AIDS is massive. 38 million people are infected with HIV worldwide with AIDS claiming three million lives a year (UNAIDS, 2004). The economic and social consequences of HIV/AIDS are also dramatic – it is estimated that South Africa's Gross Domestic Product (GDP) will fall by 17% by 2010 as a result of AIDS (Archibugi and Bazzarri, 2004).

PDPs are being promoted as a means of incentivising development of health products for a number of other similar diseases from malaria to lesser known diseases such as Chagas disease (a tropical parasitic disease). These 'neglected diseases'[10] are those that predominately affect populations in developing countries who lack the purchasing power to buy the medicines they need and as such are diseases which do not trigger significant market incentives to stimulate private sector investments into R&D. However, the make-up of a PDP is contested and the reasons put forward for their promotion have also been criticised. I will now outline how PDPs are defined in the health policy literature, the arguments put forward for their use as an incentive mechanism for neglected disease product development and some of their problems. I will then discuss how this leads to my research question regarding how collaboration takes place within a PDP.

2.1.1 Defining PDPs

PPPs are not easy to define as they refer to many different types of entities resulting in little consensus as to what a PPP means (Ridley, 2001). Huxham (1996) argues that it is difficult to tell a partnership from coordination, a coalition, an alliance or a network. The dynamic nature of PPPs has resulted in numerous categorisations being used to classify types of PPP (Buse and Walt, 2000b). These range from focusing on their organisational or institutional form to the activities that they implement and outcomes (Bustreo, Harding, et al., 2003; Kickbusch and Quick, 1998; Mitchell-Weaver and Manning, 1990; Smith, Brugha, et al., 2001). A goal orientated categorisation was deemed most relevant by Buse and Walt (2000b) in their often cited paper on the nature of global or international PPPs. This categorisation divides PPPs into those that are product based (the donation or distribution of existing products), product development based (the creation of new products) and issues or systems based (raising awareness, funds and capacity building).

[10] The definition of what is classified as a 'neglected disease' is contested (Burri, 2004; Caines, 2004; Caines, Buse, et al., 2004) but often includes the 'big three' diseases of HIV/AIDS, tuberculosis and malaria alongside lesser known diseases such as human African trypanosomiasis, Chagas disease and leishmaniasis. There has, in recent years, been an attempt to reclassify the term 'neglected diseases' to refer simply to a list of 15 of these lesser known diseases and not include the 'big three' (c.f. Hotez, Molyneux, et al., 2007)

PPPs have been defined very broadly as a relationship involving at least one private and one public sector player with a mutual sharing (although not necessarily equally) of risk and benefits (Widdus, 2003b). A global PPP has been defined in similar terms but which "transcends national boundaries… to achieve a shared health-creating goal on the basis of a mutually agreed division of labour" (Buse and Walt, 2000a:550). This concept acknowledges the idea of 'international health'; health issues are seen as increasingly complex, ignoring territorial boundaries and requiring solutions that take account of the spatial, temporal and cognitive changes occurring through the process known as 'globalisation' (Lee, Buse, et al., 2002).

IAVI is an example of a PDP being involved in product development activities. As outlined in Chapter One it has a different make up at an international level as it does at a country level. In both, as I will discuss, it exhibits aspects of a PPP because it either partners with the private sector or conducts private sector type activities.

Such PDPs are increasingly seen as attractive mechanisms to incentivise product development. A number of mechanisms to promote access to medicines have been suggested including tax credits and fast tracking of product registration (push mechanisms) or advance purchase funds and enhanced intellectual property rights (pull mechanisms) (Mrazek and Mossialos, 2003). Such mechanisms are currently the focus of many discussions surrounding vaccine development especially with regard the benefits of the demand pull mechanism of advance market commitments (Barder, Kramer, et al., 2005) whereby governments and others contribute to a pot of money that will then be used to guarantee the purchase of drugs and/ or vaccines once they have been produced. Examples of initiatives that are based on this idea are the International Finance Facility on Immunization (www.iff-immunisation.org), UNITAID (www.unitaid.eu) and the Global Drug Facility (www.stoptb.org/gdf).[11] However, for AIDS vaccine development these mechanisms often occurred in conjunction with or are passed over in favour of the use of the hybrid mechanism of a PDP approach (Mrazek and Mossialos, 2003).

[11] Websites last accessed on 11/12/07

2.1.2 Explaining the rise of PDPs

The argument for the use of a PDP mechanism to incentivise neglected disease product development tends to be framed in standard neoclassical (micro-) economic terms as one of market failure[12] as a result of the lack of market forces to ensure health solutions for these diseases are produced following traditional market mechanisms i.e. by the private pharmaceutical sector. The simplest way of explaining this argument is that supply does not equal demand because of problems affecting both the supply and demand side. Innovation towards an AIDS vaccine should follow patterns similar to pharmaceutical innovation more generally as outlined in Figure 2.2.

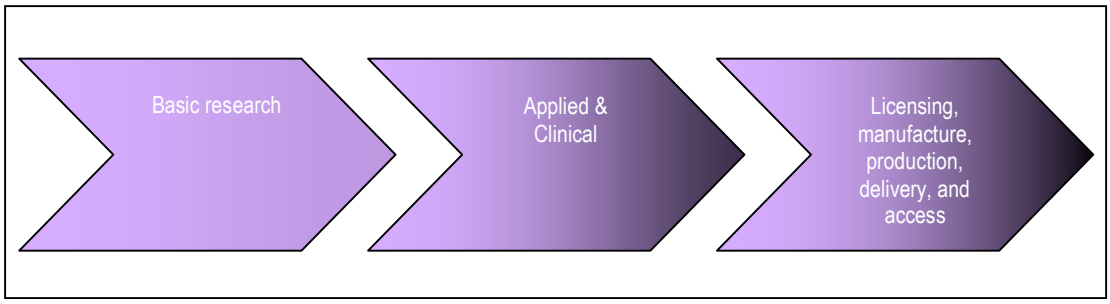


Figure 2.2 Traditional drug and vaccine development pipeline

Traditionally innovation for pharmaceutical products has occurred in a number of different stages. Initial basic research, or the identification of diseases, immune response and epidemiological surveillance, is conducted in public research laboratories and academic institutions before it is then moved into the private pharmaceutical sector for applied research and clinical development activities (production of a vaccine and its clinical testing) and commercialisation including licensing, manufacturing and delivery (IAVI, 2007b; Pisano, 2006). The

[12] The notion that there is a market failure for neglected disease vaccines is contested. It is often argued as one of missing markets (Rosiello and Smith, 2004). It is not the focus of this thesis to investigate this claim but to consider other possible explanations for the use of partnership mechanisms. The emphasis is on the way creating incentives (and thus potentially combating market failure) is the major reason put forward during considerations of PDPs activities rather than a focus other more social oriented reasons. This is despite an acknowledgement of the importance of social process in explaining the need for partnership mechanisms in the theory used to justify PDPs.

involvement of the private sector in AIDS vaccine development is important since most applied research capability resides in the private rather than public sector (IAVI, 2004). Private sector involvement in vaccine development has increased recently with developments in technology and new patentable vaccines (Batson, 1998).

Despite some positive developments private sector involvement, financing and innovation remains low especially with regards AIDS vaccine development.[13] Most AIDS vaccine research is therefore currently conducted in the public sector with public sector (including philanthropic) funds. Currently AIDS vaccine research is conducted by the US National Institutes of Health (NIH), smaller groups of researchers around the world (including some private pharmaceutical activity) but most noticeably since 1996 by the PDP, IAVI. IAVI is the largest organisation focusing on HIV/AIDS vaccine research and is the second largest program after NIH (Priddy, 2007) but is dwarfed by NIH when compared in budget terms.

In 2005 total funding for HIV/AIDS vaccine R&D was estimated at $759 million, provided mostly through US public funds ($574 million), of which 90% (US$ 511 million) was accounted for by the NIH activities (HIV Vaccines and Microbicides Resource Tracking Working Group, 2006). By comparison IAVI's projected spending for the next five years (2007 – 2011) is US$459 million and its individual revenues received for its HIV/AIDS vaccine development efforts were US$81 million in 2006 (aidsfondet, ; IAVI, 2007a). Current investment for AIDS vaccine research stands at only half the estimated budget of US$1.5 billion that is required every year for approximately the next 15 years if an AIDS vaccine is to be developed (Archibugi and Bazzarri, 2004). This lack of private sector funding is an example of this market failure and occurs despite most applied research expertise residing in the private sector. The reasons put forward to explain this market failure in relation to AIDS vaccine production are outlined in Box 2.1.

[13] This has the potential to be further exacerbated following the suspension of a Phase IIb Merck AIDS vaccine trial in 2007. The scientific uncertainty surrounding AIDS vaccine development is a further issue taken on board by pharmaceutical companies in making decisions about research areas to invest in.

Box 2.1 Market failure in AIDS vaccine production[14]

Technology based factors (hampering science/discovery push)

Natural monopoly – high fixed costs of new technology R&D, e.g. the cost of clinical trials, produce a barrier to entry and create a situation where only one firm serves the market.

Time lags - the period of time from vaccine discovery to market can take 20 years reducing companies' willingness to invest, especially when unsure of the output.

Tacit knowledge - this knowledge is hard to formulise and communicate to others and therefore suffers from high transaction and governance costs of knowledge translation and dissemination.

Economics based factors (constraining demand-pull)

Positive externalities – such externalities refer to the fact that third parties can benefit from vaccination programmes. Individual consumers and governments may then under value the need for vaccination because of assumptions regarding the (low) probability of infection and disease prominence

Information asymmetry – this relates to the uneven flows of information in society and the ability to know necessary market information.

Lack of purchasing power – the lack of consumer purchasing power (and thus potential market) can reduce the likelihood of a return on private sector investment.

Market failure is a driver of PPP formation which has been termed an example of a 'wicked problem' (Wildridge, Childs, et al., 2004) or 'metaproblem' (Rod and Paliwoda, 2003). Such problems are complex in themselves and in the methods required to solve them (Wildridge, Childs, et al., 2004) with actors having to work together in order to rectify them; crossing traditional organisational boundaries. The result is that there are not only economic arguments put forward for their role in reducing market failure but also social theory based arguments relating to the collaborative process itself. On the one hand it is argued that PDPs are a market based or economic solution that can overcome the market failure associated with neglected disease product development due to their ability to reduce the costs, externalities and uncertainties involved in making market transactions (Rangan, Van Wassenhove, et al., 2003). On the other hand social theory highlights how collaboration is important because actors work together to solve problems and

[14] This information was condensed from England (2000), Milstein and Candries (2000), Rosiello and Smith (2004), Fox-Rushby (2004), Kramer (2000) and Batson and Ainsworth (2001)

provide a means of overcoming this market failure. I will now discuss these economic and social arguments put forward to explain the rise of PPPs, and PDPs in particular, as a means of overcoming market failure in greater depth. I will then explain some of the criticisms put forward of PPP mechanisms.

2.1.2a The economic argument for PPPs

'Standard' economic theory is based on the assumption that a perfect competitive market driven by the self-regulating mechanisms of supply and demand is efficient (Slater and Tonkiss, 2001). It is generally accepted, however, that the healthcare market is not perfectly competitive (Rice, 1998). In particular healthcare markets suffer from information asymmetry (one actor has more information than the other), bounded rationality (not all problems are known and can be accounted for) and the potential for opportunism (the promotion of self-interest) (McPake, Kumaranayake, et al., 2002). The extent of these problems and the costs to find solutions to them will determine if an organisation makes or buys its goods (Coarse, 1973); the costs of transacting successfully in the market place will determine the type of institutional arrangement most profitable to actors (see McPake, Kumaranayake, et al., 2002). Institutional economics argues individuals come together and develop institutional arrangements because they reduce the transaction costs of an individual's involvement within the market – it becomes efficient to integrate and institutionalise (North, 1990). Williamson (1985) argues the type of institutional arrangement (market, hierarchy, integration) is dependent on the degree to which contracting is required as a result of uncertainty, information failures and bounded rationality. While integration assumes network based relations, networks per se (and by extension partnerships) are neglected in this assessment (McPake, Kumaranayake, et al., 2002). Networks or 'constructive partnerships' (Rangan, Van Wassenhove, et al., 2003) are deemed useful when there are positive externalities whereby there is a greater public benefit than private benefit, when there is high uncertainty for private actors (for example the lack of a potential market, long time-frame to market and information asymmetry) and high costs including the governance costs to contract, coordinate and enforce activities. As outlined above in Box 2.1, these externalities and uncertainties exist in relation to AIDS vaccine development.

As such, there is a lack of economic incentive for the private sector to invest in the development of vaccines for diseases such as HIV/AIDS affecting developing countries. However, private sector involvement is necessary because, as I outlined above, the expertise for vaccine development – especially for applied research – lies within this sector (IAVI, 2004). At the same time, the issue of positive externality has been used to argue that vaccines for diseases such as HIV/AIDS are examples of Global Public Goods and as such require public sector involvement in their financing and delivery (Archibugi and Bazzarri, 2004).[15] There is a need for both the public and the private sectors to be involved in efforts to prevent a disease such as HIV/AIDS. Economic theory therefore suggests that a global PPP such as IAVI is a useful mechanism to produce a tangible output of an AIDS vaccine.

2.1.2b The social argument for PPPs

While a global PPP may be the best mechanism for the production of an HIV/AIDS vaccine for Africa because it requires both the public and private sectors' involvement, it has been acknowledged by some economists, that such partnerships are only successful if they take into account issues of trust and reciprocity. The issues of trust and reciprocity are seen as components of social capital or the norms and networks that produce collective action. The social capital argument is one aspect of social theory that explains the usefulness of PPPs in producing tangible and intangible outputs. A second aspect of social theory that requires discussion is social network theory and its associated theories regarding the inevitable rise of networks. I will now discuss each of these issues.

It is argued that society has fragmented (Engberg, 2002) so that the policy process is no longer a hierarchical process but is increasingly interactive (de Jong, 1996). Organisational management theorists illustrate this change with the rise of the 'stakeholder society' (Metcalfe, 1998:30) while social network theorists talk of the rise of 'network society' (Castells, 1996). The world is seen as a 'shared power

[15] The degree to which a vaccine can be public good can be contested. As with most goods access to the product can be restricted.

world' (Bryson and Crosby, 1992) in which groups collaborate because they can achieve more together than they can apart (Bazzoli, Stein, et al., 1997). This assertion that actors are better served when better connected is a form of social capital (Burt, 2002). Putman (1993:167) has defined social capital as "features of social organisation such as trust, norms and networks, that can improve the efficiency of society by facilitating coordinated actions". Social capital is seen as a resource which augments productivity being similar to (Chataway and Allan, 2000) or possibly producing (Field, 2003) human or financial capital.

Social capital and social network theory view the market in normative terms; the market is more than just economic exchange and action by rational individuals. Social theory acknowledges the 'embeddedness' and 'institutedness' of the market as promoted by Polanyi; the extent to which social and institutional relations influences actors' behaviour within the market as individuals and as groups (Slater and Tonkiss, 2001). However, as a result, not all partnerships or networks are necessarily useful. Networks can be costly due to decision costs, blockages and free riding by others (Rico, Saltman, et al., 2003) while hands-off regulation in the form of 'governance' can lead to increased bureaucratisation. This supports Michel Callon's argument that although markets may initially disembed actors, disentangling them from their social ties; entering them into the market can re-embed actors into new contexts (Slater and Tonkiss, 2001). In acknowledgement of 'the social', there have been attempts to distinguish different types of social capital with the development of bonding and bridging social capital (Putman, 1993). Bonding social capital relates to close ties between similar groups of people and bridging social capital refers to more distant (weak) ties between similar people (Field, 2003). Increasingly there is acknowledgement that bridging ties may be more preferable to stronger bonding ties (Slater and Tonkiss, 2001). Weak ties are more informal extended ties (Granovetter, 1973) as such they require a deeper initial degree of trust which cannot be assumed.

Neither of these examples of bonding or bridging social capital can be used to effectively describe the global PPPs related to AIDS vaccine development. These partnerships involve a range of public, private and civil society groups who are not

similar and who network in order to integrate their various competitive advantages. They are instead examples of what have been termed 'linking social capital' (Szreter and Woolcock, 2004). Linking social capital "reaches out to unlike people in dissimilar situations, such as those who are entirely outside the community, thus enabling members to leverage a far wider range of resources" (Woolcock, 2001; see Field, 2003:42). Szreter and Woolcock (2004) see linking social capital as providing a bridge between different attitudes towards social capital by addressing issues of quality of health services and access to material resources. IAVI is made up of 'unlike groups' from the public, private and civil society sectors; leveraging each other to ensure a wider range of resources are available for the development of an HIV/AIDS vaccines and access by developing country populations to these vaccines. Recognition of the need to work within the context of a 'network society' where more can be achieved together than working alone creates the intangible output of 'social capital' or increased collaboration that ultimately allows for the production of the tangible output of an AIDS vaccine.

2.1.3 The problem with PPPs

The linking concept acknowledges the normative dimension of social capital – its embeddedness and institutedness – by making power relations explicit. Members' appreciation of the network and each other is built on knowledge of their different social identities and their "institutionalised endowments of power and resources" (Szreter and Woolcock, 2004: 656). Power relations have been underestimated by many social capital theorists (Field, 2003) but acknowledged by many who have investigated the rise of international health global PPPs. In particular, the lack of formal internal governance or rules of working has been a major criticism of global PPPs as exemplified by the Roll Back Malaria Partnership External Evaluation (Yamey, 2002). The issue of power is central to the problems of information asymmetry, bounded rationality and opportunism that result in market failure.

Aspects of both economic theory in the form of institutional economics and social theory acknowledge that the perfect market cannot operate exogenously from the rest of life and society. Despite this, theory is too reductionist; working within an 'info-

theoretic economy' (Stiglitz, 1994) with behavioural issues still related back to the economy through informational problems (see Fine, 2001). Taking this argument one step further Fine argues this has resulted in social capital being used as a concept to divert attention away from economic theory, leaving it unchallenged. This tension between Socialism and *laissez-faire* (Fine, 2001) brings us back to the work of Polanyi (Taylor-Gooby, 2003). Although the acknowledgement of 'the social' may mean economic theory is left unchallenged, understanding the 'embeddedness' of the market in society is important if it is not to become self-destructive. In Polanyi's view free markets will not work in the long run as they will be undermined by the conditions of their own success (its disembeddedness) leading him to the conclusion that government intervention is required (Taylor-Gooby, 2003).

The need for intervention has also been identified by Szreter and Woolcock (2004). Even in a situation of linking social capital, the problems that result from market failure and the associated behaviour of actors within the market place require a role to be played by the state in regulating the system to ensure quality and access issues are addressed (Szreter and Woolcock, 2004). However, the regulator in a healthcare system may become influenced by the organisation it tries to regulate ('firm capture') or by the government on whose behalf it is supposed to regulate ('government capture') (Goodard, 2003).[16] This is however less likely in global PPPs because, by definition, these work outside national government boundaries. However, institutional capture may still occur at international level with organisations such as the United Nations; with limited resources, they may face institutional capture from more powerful actors (Buse and Waxman, 2001) and will still be bound by national level rules and regulations.

The difficulty of regulating internal power dynamics especially when the motivations between the public and private sector are at odds has led to suggestions that global PPPs should only involve the private sector when they are producers of health or profit from "better health" (Hancock, 1998:194). Although this is not to say that it is only the private sector who may hold most power in these relationships, it does

[16] Goddard is actually referring to the situation within the UK National Health Service but the concepts are useful in their generality to explain the possible situation faced by any regulator.

suggest that not all partnerships are necessarily desirable especially when issues of equity and ethics are involved (Roberts, Breitenstein, et al., 2002). Issues of equity and ethics are raised not only because there are irreconcilable motivations of different partners or unequal power dynamics as a result of opportunism, bounded rationality and information asymmetry. Partnerships may not be desirable if there is inequity and ethical dilemmas relating to the effects of these global PPPs on those they are meant to help. There are concerns that some global PPPs may accentuate inequalities within and between countries if partnerships are created only if there is the chance of a successful outcome. Countries are chosen because of their favourable geographical, political and social conditions (Walt and Buse, 2000). PPPs are often seen as creating focus on short term gains, vertical programming and single diseases to the neglect of overall health systems (de Savigny, 2004) and the possible abdication of responsibly by states for their population's health (Buse and Waxman, 2001).

2.1.4 The reasoning for PPPs and my first research question

The argument for PPPs is therefore based on the premise that this mechanism brings together the correct balance of actors from within the private and public sector to incentivise the production of required neglected disease medicines. Partnerships are deemed economically advantageous mechanisms as they reduce the costs and risks involved and are socially useful because they increase networking improving trust and reciprocity. These arguments, particularly the social theory for PPPs and partnership, acknowledge the importance of these institutional relations and the normative dimension of them as a result of their embeddedness within wider society. However, despite this and as I outline above in addressing the problems of PPPs, rarely are these normative issues discussed in relation to the progress of PDPs. Discussions stress the incentivising role of the partnerships to produce new products rather than spending time asking how the partnerships work. More specifically, there have so far been few studies that have considered the institutional relationship between partners within a PDP from the perspective of the developing country interactions.

The role of process therefore becomes 'black boxed' (Mosse and Lewis, 2005). As a result I look inside the black box and ask in my thesis how collaboration within a PDP occurs? In this thesis I discuss who needs the PDP collaboration and in what ways does the collaboration take place? I was particularly interested, following on from my MSc dissertation on SAAVI, to look at the relationship between IAVI and its partners on the ground in Kenya.

Research question:

- **How does collaboration occur in a PDP?**

In undertaking institutional level analysis of one PDP, it is possible to consider how collaboration and knowledge exchange takes place and how best collaborative activities through partnership can be conducted. More specifically, in this thesis I consider not only 'economic' incentives but also less market orientated 'social' incentives to ensure partnerships work well. Such analysis has rarely been considered within the literatures particularly in terms of health partnerships. Studies of health partnerships have often taken the form of general (global) governance[17] analysis and recommendations about PPPs (c.f. Buse and Harmer, 2007; Buse and Walt, 2000b; Caines, 2004; Caines, Buse, et al., 2004; High-Level Forum on the Health MDGs, 2005). Except for official evaluation reports, there are only a few studies that consider the actual day-to-day workings of a global health PPP (not all of them look at a PDP structure or in developing countries). Such studies are found in Reich (2002), include those by Muraskin (2004; 2005) or Peters and Phillips (2004) and more lately the study of the African Comprehensive HIV/AIDS Partnership (Ramiah and Reich, 2006). There has been some initial review of IAVI's activities (Chataway and Smith, 2007; Chataway and Smith, 2006; Solnick, Ajayi, et al., 2003) but these have not focused on IAVI's activities in Kenya and have instead considered the activities of the international version of the IAVI partnership.

[17] 'Governance' is defined by Buse (2004), following Rosenau (1995), in this context as the way an institution 'steers' itself or the rules and decision-making used to control and ensure authority.

More institutional level analysis at the micro or country level of PDPs is important if partnerships are to remain a dominant mechanism within the development and health policy landscape (as they seem to be) in order to build up a solid literature on which recommendations for best practice can be based. Thus in this thesis I conduct an institutional level study of the IAVI partnership in Kenya to "[investigate alternative] representations and practices in concrete local settings" (Escobar, 1995: 19) working within the 'spirit of ethnography' to examine the realities of collaboration and capacity building and the complex and nuanced interconnection of forces, actors and relationships at work.

2.2 Theme 2 – The linkage between innovation and health

IAVI is an example of a PDP created in order to incentivise product development in the area of neglected diseases. Following standard innovation theory (c.f. Schmookler, 1966; Schumpeter, 1934) various incentive mechanisms aimed to push supply or pull demand of pharmaceutical innovation in the area of neglected diseases have been put forward as discussed in the previous section. Weighing up which incentive mechanism to focus on has recently been the role of an Intergovernmental Working Group on Public Health, Innovation and Intellectual Property. Set up in 2006 by the World Health Organisation (WHO) after lobbying from developing country governments, NGOs and concerned researchers, the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property's role is to follow up the recommendations of an earlier WHO Commission for Intellectual Property Rights, Innovation and Public Health. This 10 member Commission was a time limited (2003-2005) body tasked with reviewing the linkages between intellectual property rights, innovation activities and public health. The Commission's report provided an in-depth review of the potential of pharmaceutical innovation for neglected diseases but also the obstacles faced, particularly by developing countries. The role of the Intergovernmental Working Group is to work towards the creation of a framework that identifies important R&D priorities for the

production and access to medicines (drugs, vaccines and diagnostics) and their appropriate funding mechanisms based on the work that has gone before in this area.

What is particularly interesting, in relation to my thesis, about the work of the Intergovernmental Working Group and particularly the WHO Commission before it, is the example it gives of the multiplicity of actors involved in promoting and working with, or inside, the PDPs for neglected diseases. The Working Group and the Commission have been influenced by increasing interaction of a small group of researchers and practitioners from the health, innovation and international development fields around the concepts of 'health innovation' and 'health research' for neglected diseases. 'Health innovation' refers to the production of science and technology that benefits health as well as new policies regarding healthcare provision activities (Morel, Broun, et al., 2005). In this thesis, unless otherwise stated, a narrower definition will be used whereby health innovation refers only to the process of producing health products or technologies such as drugs, vaccines or diagnostics. This builds on the traditional idea of 'innovation' as the production of new and useful (marketable) knowledge (science) or products (technology) (c.f. Freeman, 1982). The term 'innovation' is often used synonymously with the term 'R&D' and this thesis will also use them interchangeably. 'Health research' refers to "the generation of new knowledge using the scientific method to identify and deal with health problems" (Commission for Health Research for Development, 1990: 13) and is seen as including not only biomedical scientific research into new products (or what I define above as 'health innovation') but also what is referred to as 'health policy and systems research' that refers to new policies or approaches regarding healthcare provision activities (WHO, 2004).[18]

Individuals who are coalescing around discussions of health innovation and health research come from two main fields. They include those either involved in the production of, or who research, science and technology or are people involved in the production, or research, of global health policy (not only the written content of

[18] I am using a narrower definition of health innovation in this thesis because, as I will discuss later in this section, rarely is healthcare provision or related policy discussed at the same time as innovation despite its inclusion in these new definitions.

international health policies or documents such as by the UN or others but also the processes by which such policies are produced).[19] In particular, researchers taking an innovation studies perspective within the STS and international development communities have started asking: what potential do biotechnologies have for developing countries in meeting the Millennium Development Goals (MDGs) (Singer and Daar, 2001), how can developing countries develop their science and technology capacity to innovate in the area of health technologies (Morel, Broun, et al., 2005) and, what are the determinants of successful health innovation and can health innovation systems be developed? (Chataway, Chaturvedi, et al., 2007; Mahoney and Morel, 2006; Mahoney, Krattiger, et al., 2007). In particular PDPs are being seen as a form of health innovation system termed a 'health innovation network' made up of all the entities required to promote development of certain health products and which in turn has beneficial consequences for the innovative capability of the country (Chataway, Chaturvedi, et al., 2007; Morel, Acharya, et al., 2005). This term I explore in more depth in Chapter Four.

Those within global health policy have taken as their starting point the notion of 'health research' and the acknowledgement of the 10/90 gap which refers to the fact that only 10% of health research funding is spent on health research relevant for developing countries but where 90% of the disease burden is found (Commission for Health Research for Development, 1990). These researchers have been asking how can the 10/90 gap be reduced (Davey, Jupp, et al., 2004), how can health research capacity be strengthened (Nuyens, 2005), can health research systems be developed (Pang, 2003) and how do we close the 'know-do gap' between what is known and what is actually carried out (Pang, Pablos-Mendez, et al., 2004)?

These two sets of researchers have started interacting with international public health practitioners through the WHO Commission on Intellectual Property Rights, Innovation and Health and an annual conference held by the Global Forum for

[19] As Gill Walt (1995:1) has highlighted "For most people, health policy is concerned with content. The best method of financing health services (private vs. public insurance systems for instance) or about improving antenatal healthcare delivery" however it is also "about process and power…[i]t is concerned with who influences whom in the making of policy, and how that happens" on the international stage.

Health Research, an international independent foundation established in 1998 with the aim of increasing the focus placed on health research encouraging new funding and resources to be channelled into the key priority areas. The Global Forum for Health Research's annual meeting provides an opportunity for questions around health research and innovation that are starting to be asked by these newly integrating groups of researchers and practitioners to be discussed.

However, these areas of scientific and technological research or innovation and health have traditionally been viewed as separate and are based on differing starting premises of economic development and social justice. In the past, there have rarely been integrated policy initiatives between the two areas of innovation and health as the relationship between innovation and health has in the past rarely been acknowledged. Policy is still often conducted in discrete silos where health and innovation activities are viewed in the context of separate 'systems'. For example, science and technology innovation has been considered from a macro-economic perspective in terms of its role in promoting the economic development of countries and health issues have not come into policy discussions. A stress has traditionally been placed on building industrial and technological capacity and more particularly capabilities in countries to ensure economic development. Health was until recently[20] seen as unimportant in development. Science and technology policy has not generally focused on health related matters because health has not been strategically important to national growth in many countries (Freeman and Miller, 2000).

From the other side in the global health policy field, the science and technology inputs required for healthcare provision have been discussed but without

[20] It is debateable as to when the shift started. Some state as early as 1977 and the World Health Assembly's Health for All strategy and the later signing of the Alma Ata in 1978 (Ritsatakis, Barnes, et al., 2000). This is an argument advanced by Abel-Smith and Leiserson (1978, see Commission for Macroeconomics and Health, 2001:114). However, Susan Rifkin at London School of Economics in a lecture in 2003 argued the resurgence of these issues occurred with the rise of the World Bank in global health policy and the publication of its 1993 World Development Report entitled 'Investing in Health'. Regardless of the starting date for this change, this change is occurring as evidenced by the more recent 2001 WHO Commission on Macroeconomics and Health (a two year 18 member body assisted by working groups that analysed the impact of health on development).

acknowledging the interplay between the two sectors. For example, issues of pharmaceutical R&D have been discussed, particularly by health economists (c.f. Batson, 2002; Moran, 2005; Mrazek and Mossialos, 2003), lobbyists such as Medicins Sans Frontieres have campaigned for access to medicines for populations in developing countries, while others have considered (not always positively) the use of public-private partnerships to ensure drug and vaccine access (Buse and Walt, 2000a; Kettler and Marjanovic, 2004; Nwaka and Ridley, 2003; Walt and Lush, 2001; Widdus, 2003a). However, they have not until recently considered issues of how innovation takes place. As such, much global health policy, building on neoclassical based health (micro-)economics, has traditionally viewed innovation in terms of the finished products (such as drugs, vaccines and diagnostics) and their role as inputs to aid healthcare activities with a focus being on social justice and the ultimate goal of reducing burden of disease. In recognition of this the WHO's World Health Report in 2000 highlighted how the term 'health system' is used to refer to the components necessary to ensure better health and thus are seen in terms of the provision and investment of healthcare. Thus, 'health systems' tend to refer to health*care* systems and do not acknowledge wider areas of activity such as health innovation.

The creation of the Intergovernmental Working Group, the work of the Commission on Intellectual Property Rights, Innovation and Health, and the activities promoted by the Global Forum for Health Research in particular, which have enabled researchers and practitioners from these different fields to come together albeit from the related but separate starting points of health innovation and health research, are testament to the fact that innovation and health are in fact interlinked areas of concern. My fieldwork account at the start of Chapter One also highlights the practicalities of this interaction for those working on the ground in clinical trial research.

During my fieldwork I found that, when one considers the clinical trial aspect of such research, scientific research on AIDS vaccines does not occur in isolation to healthcare activities. The partners involved include those involved in traditional

innovation activities or scientific R&D of vaccine development but also healthcare providers on the ground in clinical trial settings and the surrounding communities. It is impossible for AIDS vaccine research to take place in Kenya without a collaboration occurring between these different entities.

Yet often, as the account at the beginning of the last chapter highlights, collaboration's process is overshadowed by the focus on developing the end-point; on ensuring the availability of an input for the healthcare sector as per much of the health policy literature discussed above. This is the case with much of the literature that suggests ways forward for reducing the problem of neglected diseases is for more drugs and vaccines and better diagnostic techniques. For example, the solutions put forward towards the MDGs or the Gates Foundations' Grand Challenges in Global Health often focus extensively on the need to develop new health products. The result is that the interaction between innovation and health occurs as a result of the scientific community providing the healthcare community with a new health product input in the form of a new drug, vaccine or diagnostic. As I shall discuss in Chapters Five and Six, this fits into a wider debate regarding international development assistance approaches and a changing focus in recent years towards results and outputs and away from process mechanisms with the rise of neoliberalism.

The popular mechanism to be used to develop such health inputs are PDPs as discussed in the last section. These PDPs not only result in an interaction between those involved in innovation and health by creating new health inputs, but in conducting their activities create a new form of interaction between these two traditionally separate groups. As this thesis will show, the case study of IAVI highlights how the process by which PDPs are promoted (using a private sector pharmaceutical model) creates a situation where the focus on the end-point is intensified and activities have been carried out in the past only as required to ensure the successful development of the candidate vaccine. In so doing, there is a required interaction between those involved in research or innovation and those traditionally involved in healthcare activities. This is a different form of interaction than that

which has traditionally taken place between actors involved in these two spheres. The Kilifi District Hospital does not simply receive the vaccine for use in its immunisation schedules at the end of a product development pipeline. Instead, the hospital staff members are bound up in the process of the vaccine's development while those involved in the innovation actions, the research staff, have to consider healthcare related questions, such as volunteer access to ARVs, and not just the scientific questions. Thus there is not one but two types of interaction that take place between those involved in innovation and those involved in health in these situations. It is not simply an interaction revolving around a health product as an input but is about a much more nuanced and long-term interaction throughout the product development process.

2.2.1 The innovation and health linkage and my second research question

The fact that there are these two different ways of interpreting the relationship between innovation and health was highlighted, as noted earlier, during my MSc dissertation. In particular my study of SAAVI for this dissertation identified this second area of linkage between innovation and healthcare actors and the role of knowledge exchange as a linkage mechanism between these actors. In my MSc dissertation I started to discuss the role of knowledge exchange, using the concept of absorptive capacity from innovation studies, to discuss the way it is possible to bridge the gap between the areas of innovation and health which have often been seen as separate in policy spheres and the relationship between which is rarely considered in practice. In particular, I was interested in the idea of 'absorptive capacity' or a firm's ability to recognise the value of knowledge, acquire, assimilate, and apply it (Cohen and Levinthal, 1990). Partnership activities are deemed to improve a firm's absorptive capacity by extending the range of knowledge available and increasing the resources used in innovation (Scott, 2002), providing new learning that further builds absorptive capacity (Cohen and Levinthal, 1990). This aspect of innovation theory would suggest that collaboration is important for success and is an important form of 'value added'. In my MSc dissertation I argued that although SAAVI is not a firm, each individual organisation within SAAVI can be seen to

represent the equivalent of a firm and therefore benefits from and creates absorptive capacity through its SAAVI membership.

Thus, in my PhD I develop this idea further by asking specifically about the type of collaboration that takes place between the different groups involved within a larger more established PDP such as IAVI. I ask if the interactions within a product development partnership lead to interactions between those involved in health and those involved in innovation and what type of interactions these would be?

Research questions:

1. **Do interactions within a product development partnership lead to interactions between those involved in health and those involved in innovation?**
2. **If so, what types of interaction take place?**

I ask these questions so that I can look more specifically at this knowledge-based relationship between innovation and healthcare and consider if it exists in a different product development PPP. In so doing I am able to contribute to a gap in the literature on health innovation around product development partnerships by discussing the role of knowledge based process capacity, a term I define in the next section and which I use in part due to a reading of the innovation systems literature from which the notion of absorptive capacity developed.

There is an increasing focus being placed on the need for collaboration as a means of combating the market failure within product development for neglected diseases; product development partnerships are seen as the means through which to ensure drugs, vaccines and diagnostics are produced and reach those who need them. However, the result is, rightly, a focus on the end point – getting drugs and vaccines to those who need them – but at the expense of the in-depth study and consideration of the process taken to develop these health products. This is despite the fact that those practitioners and researchers who come from the STS community are

considering the issue of health product development for neglected diseases from an innovation systems perspective, promoting the creation of these in developing countries and using the example of successful 'innovative developing countries' as examples (c.f. Morel, Broun, et al., 2005; Morel, Acharya, et al., 2005). Such a perspective has at its core a focus on collaboration's process and knowledge exchange.

The innovation systems literature places an importance on the second form of linkage between innovation and health actors and not just the first in relation to endpoints through the development and transfer of inputs for healthcare. In this thesis I consider if there is significant interaction between those involved in innovation and those involved in healthcare activities and more particularly if knowledge exchange occurred between those involved in innovation and health. In so doing, I address a second gap in the literature. As I have outlined above, in the past the literature, particularly from within the health policy field, has predominately considered the link between innovation and health in terms of innovation's input to healthcare provision. This is despite the acknowledgement within innovation studies of the importance of knowledge based, process forms of capacity related to the notion of absorptive capacity. While there has been an increasing interaction between researchers and practitioners from these two fields, there has been little analysis of the role of innovation as more than simply the provision of inputs to aid healthcare provision. One reason for this is because the starting questions, as outlined at the beginning of this section, are different depending on which perspective one starts from. My thesis is the first time PDP collaboration has been studied, through the lens of capacity building, to consider the linkage between innovation and health in a way other than as a provision of an input into healthcare provision.

2.3 Theme 3 – Bringing things together with scientific research capacity building

As outlined above, based on the literature related to innovation studies, and particularly innovation systems thinking, the idea of knowledge exchange and the role of absorptive capacity can be seen as important requirements for successful collaboration to take place. In this way promoting their use within and across firms and networks can be seen as a form of capacity building for those involved in scientific research collaborations such as PDPs. Discussions of what should be included in scientific research capacity building in developing countries has grown more frequent in recent years and there is increasing recognition – as knowledge management ideas take hold within the international development field (Hovland, 2003) – that there is a need to move beyond simply thinking about such assistance in terms of training and resources (Horton, Alexaki, et al., 2003; Milèn, 2001). As Trostle (2000:165) writes:

> "In summary, efforts to change the conditions of research in developing countries have focused on training more scientists and providing them with more local resources. Until recently, less attention has been paid to helping build local linkages, or creating more stable institutions."

This history of scientific research capacity building in developing countries and development assistance are strongly linked. The need to build internal scientific research capacity, particularly around R&D, within developing countries has been receiving attention since the start of colonialism, particularly after the First World War in the 1920s, and has often been synonymous with development assistance (Alvares, 1993; Trostle, 2000). In the area of health research attention on capacity building has increased over the past 15 years, particularly since the formation of the Global Forum for Health Research in 1999 (Nuyens, 2005). This programme places an emphasis on the notion of 'health research capacity strengthening' in order to close the 'know-do' gap and reduce the inequalities in health research that create the 10/90 gap discussed earlier in this chapter. As discussions of capacity building and development assistance have taken place, what is meant by these terms has changed with time.

2.3.1 Changing notions of capacity building

There has been a shift in thinking about what building scientific research capacity should entail, particularly in recognition to past failures in development assistance. It has become increasingly recognised that the huge sums of money poured into development assistance in the 1980s and 1990s had not reduced dependence on expatriate 'experts' and the development of trained cadres of professionals in many areas including the health sector (Milèn, 2001). During this time an emphasis was placed on capacity building as defined in terms of training personnel and provision of resources, as per the quote from Trostle. However, increasing scientific capacity does not only mean training more scientists or developing human capacity but also requires - for a systemic approach to capacity building to take place – an emphasis on physical capacity (e.g. laboratories and equipment), organisational capacity (e.g. management skills) and social or governmental capacity (e.g. economic, social and political support) (Csazzar and Lal, 2004).

Looking at the capacity building and research capacity literature it is possible to find other similar new definitions of capacity building that emphasise not only individual training and resource provision but also more institutional and enabling environment based activities as important forms of capacity building. For example, Landsang and Dennis (2004) suggest four approaches to improving research capacity through 'learning by doing', co-learning and the development of partnerships or centres of excellence. Oriogio (2004) highlights four processes of capacity building: development (of skills and tools not available), retooling (re-equipping and updating), enhancement (strengthening existing skills or institutions) and reform (reorganisation of skills and institutions to enhance effectiveness). He also stresses that capacity building needs to occur within a project cycle approach that ensures capacity is assessed at all stages of the project cycle and that learning and changes take place as required at the different stages of a project. Hawe et al (1997) in the context of health promotion thus identifies three levels and dimensions of capacity building. The first is infrastructure and service development (the ability of staff and institutions to deliver a particular programme). The second level is programme maintenance and sustainability (the continued ability to deliver services once the

initial programme has finished). However they stress that sustainability does not assume quality nor does it necessarily take account of the depth of embeddedness of institutionalisation that has taken place. The third level is problem solving capability of the organisation and community (the generic ability to identify problems and find solutions to these) which they liken to the concept of the 'learning community'.

These different definitions can be divided into three main types of capacity building defined by Nuyens (2005) at the individual level (this includes training but not just training in the development of technological know-how but also in leadership, networking and advocacy skills), at the institutional level (development and strengthening of institutions) and at the macro or system level (creating a supportive enabling environment and development of national health research systems).

This thesis will use and develop Nuyen's definitions further when discussing the capacity building activities that IAVI as a PDP contributes to. This is because it provides a means of holistically thinking about capacity building moving beyond simply looking at individual training and skills provision or infrastructural support. It provides a means, as per the United Nations Development Programme (UNDP) definition of 'research capacity strengthening' to consider capacity building activities as a holistic process. Capacity building or research capacity strengthening becomes in this UNDP definition:

> "…the process by which individuals, organisations and societies develop abilities (individually and collectively) to perform functions effectively, efficiently and in a sustainable manner to define problems, set objectives and priorities, build sustainable institutions and bring solutions to key national problems." (cited in Davey, Jupp, et al., 2004: 149)

However, this requires that sustainability is not simply measured in terms of longevity but the degree to which "the intervention renders the community or the partner organisation more competent" (Hawe, Noort, et al., 1997: 32). This is at the heart of the idea of institutional level capacity. Sustainability as competency is not simply something that can occur at the institutional level but also at the macro level through the creation of an enabling environment. Lansang and Dennis (2004) stress the need for political will and credibility as well as good funding sources if capacity

building activities are to survive. These are examples of ways of building a strong enabling environment.

I term these last two forms of capacity, 'process capacity'. Such capacity involves developing more than simply individual human or physical assets but is about – as the UNDP definition tries to capture – the importance of developing long term holistic processes that will enable the complete 'system' and benefit everyone involved in and affected by health research. This includes not only the research scientists but also the community volunteers involved in the product's testing and trialling, the regulatory authorities as well as the end users: the doctors and individual patients and their families.

I use the overarching term of 'process capacity' to describe institutional and macro capacity because it builds on the notion of process monitoring and evaluation which has become popular in development assistance discussions but also because of the increasing use of the term 'process' in relation to ensuring capacity building is successful. Both of these notions directly use or are comparable to ideas within the innovation systems, and related management, literatures regarding the role of learning opportunities and processes to create stronger collaborative activity to lead to business and strategic success of projects and from which the idea of absorptive capacity was developed.

Process capacity building is about the building of less tangible organisational knowledge based forms of skills and capabilities at both the institutional and the macro level which in turn impact the type of individual capacity building that takes place. Individual capacity building no longer remains simply the result of formal training but is based on more embedded organisational process capacity activities that strengthen learning and information sharing generally. I will now briefly discuss these founding notions around process and learning in more detail.

2.3.2 The rise of process perspectives

The starting place for the discussion on the rising importance placed on process is the earlier mentioned disillusionment with development aid. This is because often as discussed above, in the past, the terms 'development' and 'capacity building' have been seen as synonymous with each other in development assistance literature and policy. With the recognition in the 1990s that development assistance was not achieving 'development' or the building of long term capabilities within developing countries there was a shift in thinking within development agencies such as the World Bank, UNDP etc., about what is meant by 'development' and an interest in the mechanisms of 'development'. In particular, attention started to be paid to issues around what is required for local ownership so as to ensure quality rather than quantity of results (Schacter, 2000).

This shift was not simply the result of internal recognition within development agencies of the lack of progress that development assistance had made since its initiation in the 1950s. There was also an increasingly critical literature that was now being heard that questioned what 'development' was and how development assistance was taking place (c.f. Escobar, 1995; Estava, 1992; Mosse, 2005; Rahnema and Bawtree, 1997; Sachs, 1992). Alternative forms of development assistance were being put forward that emphasised forms of participation and local ownership (such as Robert Chambers' Participatory Rural Appraisal approach that placed local communities affected by development at the heart of development project design and evaluation). Terms such as 'bottom-up' rather than 'top-down' participation started to be used. There was also an emphasis away from specific projects to wider sectoral based initiatives. An emphasis started to be placed on building linkages between different system components that considered the evolution and life-cycle of development programmes with routine monitoring activities to allow for learning to occur throughout a programme's lifetime (Mosse, 1998). In this way an emphasis started to be placed more directly on the process or activities of development.

In relation to this last idea of routine monitoring of the life-cycle of development programmes, the concept of 'process monitoring' was developed (Scheirer, 1994; Taylor-Powell and Rossing, 1996). Assessing the whole process of a project – of 'development' – is seen as providing an opportunity to stress a dynamic and flexible system that learns as it goes along (Mosse, Farrington, et al., 1998) with the important question being not why but how development works (Mosse, Farrington, et al., 1998). This is perhaps particularly necessary for collaborative arrangements in which the process of collaboration is deemed to determine its success. For example, Alsop and Farrington (1998) argue that process monitoring is particularly useful in multi-stakeholder situations being able to measure actions, institutions, organisational mechanisms and outcomes.

Such a perspective builds on a literature from particularly the organisational management field that focuses on alliance performance monitoring (c.f. Das and Teng, 2003) and stakeholder analysis (c.f. Freeman, 1984) as ways to measure and assess the 'success' (or strength, longevity or scope for example) of collaborative activities. In particular these mechanisms make it possible to consider who is involved in a collaboration, how they are involved and what linkages they have within the networked entity to assess how information and knowledge are transferred – learning takes place – between collaborators so that the group of stakeholders can achieve their desired aims and objectives. Thus Mosse et al (1998) stress the importance of taking a learning process approach rather than a blue print approach which only emphases development of successful outcomes.

2.3.3 The role of learning and collaboration

The role of learning and its relationship to collaboration has been acknowledged in the innovation studies field, particularly within innovation systems thinking, as evidenced by the development of the notion of absorptive capacity. Thinking in this field is related to ideas developed within the organisational management field. In both fields there has been growing recognition that knowledge is a critical resource but which is not evenly distributed and requires good information systems to increase (the right type of) knowledge flow (Nissen and Levitt, 2002). As such emphasis has

been placed on the need to create learning institutions (c.f. Senge, 1990). The concept of the 'learning institution' emphasises the organisation as a system where "people continually expand their capacity to create the results they truly desire…. Where collective aspiration is set free, and where people are continually learning…" (cited in Smith, 2001). Bessant and Tsekouras (2003) have also discussed such issues in the form of 'learning networks'. These are either set up specifically for the purpose of expanding knowledge transfer or "learning occurs as a 'by-product' of network activities through, for example, the exchange of views or shared attempts at problem-solving" (Bessant and Tsekouras, 2003: 23). In each of these cases of collective learning the emphasis is placed on the process of learning. The most well-known explanation of the learning process is perhaps Nonaka and Takeuchi's (1995) learning spiral that sees knowledge transferred to organisational use through socialisation, externalisation, combination and internalisation processes. Others have talked in a similar manner about three knowledge enablers of creating, capturing and capitalising (Ichijo et al, 1998 cited in Warhurst, 2001) or about social learning cycles (Griffiths and Boisot, 2000). In particular, the linkage between individual and organisational learning is thought to crucially occur through the conversion or transfer of knowledge from tacit to explicit forms through learning. This is also seen to be boosted by working within knowledge networks (Tidd, Bessant, et al., 2005). This is illustrated by a quote from Powell (1990: 304):

> "[t]he most useful information is rarely that which flows down the formal chain of command in an organisation, or that which can be inferred from price signals. Rather, it is that which is obtained from someone you have dealt with in the past and found to be reliable."

The ability to convert raw information into usable knowledge is referred to as 'knowledge management' and to which many corporate organisations are increasingly looking as a solution for the new challenges being faced in an information age (Hovland, 2003). Knowledge management techniques have moved from focusing on improving knowledge sharing within organisations to a second generation of knowledge management looking at organisations' processes and competitive advantage within firms (Hovland, 2003). This change now places an emphasis not only on sharing technological know-how but also systemic knowledge (new systems and procedures) and strategic understanding (the mindset of managers

towards success) (Child and Rodrigues, 1996). Therefore, there is an emphasis not only on explicit or codified knowledge but also more tacit, less easily interpreted knowledge. Polanyi (1967) and Nonaka and Takeuchi (1995) highlighted the distinctions between these, and particularly the importance of tacit knowledge. The ability to transfer (tacit) knowledge between individuals and between individuals and organisations is determined by the degree of knowledge flow (Nissen and Levitt, 2002). Thus, collaboration between individuals and between organisations in a network influences the way knowledge flows because it is determines the way learning takes place, and the degree to which knowledge exchange occurs, between these different individuals or organisations.

2.3.4 Scientific research capacity building and my third research question

As we can see from the above, these two issues of the form of collaboration and the way capacity building takes place are linked particularly when capacity building is defined in terms of processes. Collaboration is determined by and impacts the degree of knowledge based process capacity that takes place. Thus it is possible, similar to Trostle in his quote at the beginning of this section (he is writing about the form collaboration takes and not capacity building per se), to highlight the importance of linkages and different forms of capacity building. This is one of the main themes of this thesis and as such it can be seen as the theme that links the previous starting point themes together. In this thesis I therefore look at scientific research capacity building because it helps us answer the questions around the form that collaboration takes within PDPs. I consider what is 'partnership' within the PDP IAVI by asking who benefits and in what way they benefit through the lens of capacity building. In this thesis I take a critical look at capacity building and look at the form it takes as a result of the collaboration. I therefore ask what form of capacity building takes place as a result of the collaboration that occurs with the PDP of IAVI on the ground in Kenya?

Research Question:

- **What form of capacity building takes place as a result of collaboration in a PDP?**

In so doing I consider the linkages that occur as a result of capacity building as well as the capacity building that results from the linkages. As such my findings address this third gap in the literature around how capacity building is defined and discussed. By taking a critical and in-depth analysis of the way capacity building takes place and in particular the different forms its takes, my findings add to the growing literature on scientific research capacity building and health research capacity strengthening. My study also adds to a wider literature that critiques the way development assistance takes place.

I add to this critical development literature in two ways. Firstly, I critically analyse the status of capacity building activities within a large, complex and multi-actor partnership. In so doing I consider if current criticisms of the new broad definitions of capacity building, such as the UNDP definition given earlier but also my own concept of 'process capacity', is too all encompassing and trying to do too much.

Secondly, in acknowledging the criticisms from the development field on previous and current capacity building efforts, I question the power and politics flows behind the collaboration that is the IAVI partnership. As such, I critically examine how partnership takes place and who benefits. This fits into a wider critique of current international development assistance practice. In particular, I examine the complexity that is exhibited within partnership activities and the impact this has on capacity building activities. However, I move beyond some critical and overtly negative accounts of current development activities particularly within the post-development school to consider if we can learn something from other epistemological frameworks that provide a means of moving forward with notions of 'development' and 'capacity building'. In particular, I look at whether ideas from within the innovation literature (and the related management literature) around

knowledge capacity are well founded and can provide a way to move beyond value-laden notions of partnership being based on less tangible forms of capacity building involving knowledge exchange – what I term 'process capacity building'.

2.4 Conclusion

This chapter has outlined the starting points and main themes that run through my thesis. Through this discussion I have outlined my research questions and my contributions to the literature. In so doing, this chapter has outlined the rise of PDPs as a way of incentivising product development for neglected diseases. These mechanisms are seen as a way of combating or overcoming the market failure that exists in this area. I have shown how, as a result of this market orientated focus, a focus is placed on the end point (the new drug, vaccine or diagnostic) at the expense of issues of 'process capacity' or the less tangible, knowledge based forms of capacity that ensure successful collaboration and knowledge exchange take place and which enable partnerships to succeed in reaching their end point.

The chapter has outlined how focusing on process capacity highlights a different form of interaction between those involved in innovation and those involved in healthcare activities. The interaction is not simply one of innovators providing inputs for healthcare actors to use but a more complex set of interactions within the product development process. This chapter therefore highlights not only the existence of 'neglected diseases' but also of 'neglected research' relating to how these interactions take place and how the process of partnership occurs. This thesis focuses on this neglected area of research by considering the interactions and knowledge exchange as a form of capacity building.

Finally, this chapter has highlighted how, by looking at this issue in terms of capacity building it is possible to place the focus of this thesis within a wider debate about the role of development assistance which is one of the functions of a PDP such as IAVI in working in developing countries like Kenya. Much of this literature is critical

about the function of development assistance and the true nature of initiatives which call themselves ‘partnerships’ but which are based on unequal distribution of resources and knowledge. Throughout this thesis I aim to study IAVI using a critical development theory lens that mixes a ‘spirit of ethnography’ based on anthropology of development ideas with thinking based on ideas within the innovation systems literature (discussed in succeeding Chapters Four and Five) to highlight the issue of the power and politics behind the collaborative efforts and how this impacts the type and form of capacity building that occurs.

Chapter Three

Methodology:

Smelling the roses

> "To know a rose by its Latin name and yet to miss its fragrance is to miss much of the rose's meaning." (Eisner, 1981: 9)

Eisner's quote comes from a paper he published in 1981 in which he outlines 10 ways in which what he terms 'scientific' and 'artistic' qualitative research approaches differ. Although the rose quote relates to an argument he makes about the different approaches towards 'knowing' – what is seen as good knowledge – I found the quote very apt in trying to get to grips more generally with what I am trying to do in my research.

Eisner goes on to write "[a]rtistic approaches to research are very much interested in helping people experience the fragrance" (p. 9). I believe that my use of certain more 'artistic' approaches, particularly an ethnographic/ anthropological rationale, is a way of trying to ensure the 'fragrance' – the nuances of my research topic – are not only outlined but that these nuances are also explained or, as Eisner puts it, that there is the production of "ineffable forms of understanding."

In this chapter I outline what qualitative research methods I have chosen and why they have been chosen. In particular, I explain my use of certain qualitative interdisciplinary approaches and how they provide a means to understand the nuanced picture of collaboration and capacity building within the IAVI partnership in Kenya. I then outline in more detail the different data collection and analysis methods I have used along with the limitations of the study.

3.1 Interdisciplinary research

In my PhD I bring together and mould various approaches to data collection as well as a variety of theoretical perspectives and literatures to conduct interdisciplinary research. This research is interdisciplinary therefore not simply because it studies an issue by using multiple theories or perspectives at the same time one after the other (Tait and Lyall, 2007). My research is interdisciplinary because it involves studying an issue by using a variety of data collection mechanisms and theories or perspectives that have been integrated together to create a hybrid approach (Tait and Lyall, 2007). My research moulds 'classic' qualitative data collection and analysis techniques together with an ethnographic or anthropological rationale. This means I study IAVI in the 'spirit of' ethnography and anthropology at multiple levels (micro, macro and meso) and go on to combine ideas from the anthropology of development literature with innovation systems thinking to explain my findings.

I have been interdisciplinary from the outset integrating two different approaches to data collection and analysis. I have used 'classic' qualitative data collection methods such as interviews and direct observations and a grounded theory approach to data analysis. I have then integrated these methods with an ethnographic/ anthropological rationale that places an emphasis on a critical approach to get to grips with the power and politics underlying activities within the IAVI partnership in Kenya. To do this I conducted my data collection and analysis within what could be termed the 'spirit of ethnography'. I have not undertaken anthropological research by conducting an ethnography defined in terms of participant observation (c.f. Burawoy, Burton, et al., 1991) but instead worked within the spirit of the approach. The spirit of an ethnographic approach is to ensure a 'thick description' (Geertz, 1973) or the in-depth study of every day practices. In particular, my PhD looks at the more micro workings of innovation and issues around capacity building and involvement – going beyond just looking at the global R&D activities of IAVI to get to grips with the implications for developing countries of participating in this type of research beyond benefiting in the long term from a new vaccine. But it is not simply about the micro level, conducting research in the spirit of ethnography is about getting as complete an

understanding of a situation as possible to grasp the nuanced relations, the politics and power that explain activities and events. My research is interdisciplinary therefore because it also integrates a focus on the micro level study of IAVI's partnership at country level in Kenya with a macro level study of the wider health and innovation policy arena. This is necessary in a study that takes place in the spirit of ethnography as it is the only way to really get to grips with all the impacts on an event as an event does not occur in isolation of wider influences external to its immediate surroundings.

It is also interdisciplinary because, in my analysis and discussion of the issues raised in studying the multiple levels of IAVI's activities in Kenya, I bring together ideas from two fields. I work with ideas from within innovation studies (more specifically from the literature on innovation systems) and with the literature from the anthropology/ ethnography of development to comprehend the nuanced relations that are behind the activities I witnessed, and heard accounts of, during my data collection. I shall now discuss these various choices of an interdisciplinary approach towards data collection, analysis and discussion in more depth.

3.1.1 In the spirit of ethnography

This research hinges around what, as this thesis will highlight, are often seen as emotive and contested concepts such as 'capacity', 'collaboration', 'partnership' and 'development'. These concepts are highly nuanced and are defined as different things by different people in different contexts which meant the research process chosen had to be iterative. To ensure that the full nuanced picture of these concepts is gained, this study used qualitative research methods that provide analysis that is "more explicitly interpretive, creative and personal" (Walker, 1985: 3). Qualitative data collection methods, such as interviews and direct observation, are better able to catch the nuances of the data required than quantitative methods such as questionnaires without detracting from the validity of the information gained; the greater the depth of the data expressed the greater the validity given to the data by the outside observer (Schofield, 1993). Qualitative research allows for these relations to be fully explored "reaching parts other techniques don't" (Walker, 1985:

18) by allowing the researcher to "[see] through the eyes of" others (Bryman, 1988). This research therefore took the form of an in-depth case study (c.f. Yin, 1994) of IAVI using interviews, direct observation and document acquisition as data collection methods. A case study of IAVI has allowed me to move beyond traditional quantitative analysis and capture the "fuzziness and complexities of the collaboration phenomenon" (Perks, 2004: 42) within partnerships and adequately take into account the context within which "relations, values and means as ends" interact in a post-knowledge age (Healy, 2001: 8).

However, although qualitative methods may ensure clearer and more in-depth vision of events, ethnographic methods of anthropology are deemed to provide not only an in-depth vision of events but also the 'fragrance' of the events to use the analogy of Eisner. Thus in conducting my data collection, during my analysis of my data and its discussion in this thesis I have worked within the spirit of an ethnographic or anthropological approach. I was unable to use a full ethnographic approach involving a long period of participant observation due to the difficulties of gaining long term access to IAVI and its partners in Kenya.

Thus, in a similar vain to much institutional ethnography of recent years that has turned its 'gaze to the West' (Rainbow, 1966 in Fox, 1998), in this thesis I examine the everyday practices of individuals within institutions in order to understand how and why people behave as they do (Moeran, 2005). Using regular qualitative methods undertaken within an ethnographic rationale, my fieldwork and data analysis, following the arguments of Gellner and Hirsch (2001), placed an emphasis on gaining an in-depth understanding of the workings of the partnerships – of the 'organisations' – and a sense of 'being there' through the use of in-depth and repeated interviews and periods of direct observation and document acquisition. Due to the inability to conduct participant observation or sustained periods of direct observation (a difficulty of researching organisations noted by Gellner and Hirsch) much of my fieldwork data is interview based. My emphasis during data collection and its analysis was therefore to mould the critical analysis that is fundamental to ethnography (the ethnographic rationale) with more general qualitative data

collection methods, particularly in-depth interviews, supplemented with observation data where possible.

At the same time this ethnographic inspired qualitative approach is complemented by an analytical inductive analytical process whereby I allow the data to 'talk for itself' (Bryman, 1988). In this way I allowed the flow and direction of the research to take its course and followed leads as and where they took me in order to gain as much contextual depth as possible. This is important because of the "constant interplay between the observations of realities and the formation of concepts, between research and theorising, between perception and explanation" that occurs during the research process (Blumer, 1982 cited in Walker, 1985).

3.1.2 Multiple levels of analysis

As I mentioned above, in this thesis I gain a more complete understanding of the nuanced relations around the activities and events of the IAVI partnership in Kenya. This requires an interdisciplinary, multi-level approach towards the case study of the partnership. This allows me to study IAVI's partnership at country level in Kenya (the micro level) and integrate it with an understanding of the meso (organisational) and macro (internationally/ globally) level activities that influence the micro level interactions. In so doing I am able to show the concepts of 'health innovation', 'health research' and healthcare activities fit together.

My thesis therefore considers the IAVI partnership in Kenya from three levels. It looks at the relations between the micro level activities of an innovation network (the IAVI partnership and its internal workings) particularly at country level in Kenya, the meso level activities of the organisational activities of health and innovation or scientific research in Kenya more generally, and the macro level international policy discussions within which the IAVI partnership is placed. However, I do not simply look at each of these levels independently of each other but consider how they influence each other.

3.1.3 Mixing innovation systems and an ethnographical rationale

In studying the IAVI partnership in Kenya from within the spirit of ethnography and from a multi-level perspective, I have come up with issues of discussion that can only be understood properly using similar ethnographic or anthropological rationale. These discussion issues include the value-laden notion of partnership, understanding the collaborations around innovation and the way learning and knowledge capacity is built. While literature from, and ideas related to, innovation systems highlight the collaborative dimensions and the importance of linkages between actors to ensure knowledge exchange, only through marrying this with thinking from within the anthropology of development will an in-depth and critical analysis of the power and politics flows that determine these linkages be possible.

The anthropology of development perspective (c.f. Crewe and Harrison, 1998; Escobar, 1995; Ferguson, 1990; Gardner and Lewis, 1996; Mosse, 2005) critically examines how international development or the provision of economic, social, technical, health or political assistance is given from one country to another to 'aid' the country's 'growth'. In particular, this perspective's role is to look at the local effects of wider macro processes, studies policy on international development as an 'ethnographic object' and reconfigures scale through an analysis of the context around relations between actors involved in regulation and policy making (Mosse and Lewis, 2005).

Thus I not only have conducted my qualitative research (data collection and analysis) within the spirit of ethnography but also my discussion of the issues that arose in this context too. My research is therefore interdisciplinary in this respect because I marry ideas from within the anthropology of development with those related to innovation systems thinking as introduced in Chapters One and Two around collaboration and knowledge exchange. Taking this interdisciplinary perspective in my discussion of the issues raised by the data does not negate the analytical inductive research process that I have used. One of the reasons, as I shall explain below, for using the framework approach to my data analysis was that it provided me with a means to objectively draw out themes or issues from the data without being influenced by pre-

existing ideas. Working within the spirit of ethnography by combining ideas from anthropology of development with innovation systems related thinking allowed me to consider more than simply the way people collaborated in the partnership and the forms of capacity building that took place once I had the main themes and issues.

3.2 Data collection methods

I spent just short of eight months during four trips in Kenya between October 2005 and November 2006. I was already familiar with Kenya and with the geographic locations where the IAVI partnership worked, namely Nairobi and the Coast province. As a result and through a network of friends, the practicalities of setting about my fieldwork (finding somewhere to stay, transport etc.) were not so difficult. I had already gained access to IAVI prior to my first trip to Kenya in October 2005 and this first trip I spent getting to understand how IAVI worked with this partners and meeting one set of partners at KAVI. During my second trip in early 2006 I finalised my research permit and got down to fieldwork more intensively starting to conduct 'official interviews' with members of KAVI and representatives of the wider clinical research and policy network and starting discussions with KEMRI-CGMRC about their relationship with IAVI organising a visit to them in Kilifi and Mtwapa. My third visit in early summer 2006 was my most intensive fieldwork phase although my focus was much more towards getting more knowledge and understanding of KEMRI-CGMRC and the wider research and policy networks. I felt at this point that having been based in Nairobi predominately on previous trips I had been able to spend more time at KAVI and talking to other Nairobi based actors within the IAVI partnership and was beginning to understand how and why they worked as they did. As I shall outline in the final section of this chapter I was unable however to ensure equal access to, or get a similar understanding of, KEMRI-CGMRC as I had with KAVI in one visit.

My final visit in the autumn of 2006 was spent following up with everyone I had talked to, presenting my preliminary findings and getting feedback. Prior to arriving in Kenya I decided that I would send everyone I had interviewed a copy of a

preliminary findings report I had put together. When I arrived in Kenya I arranged to have specific one to one meetings with a number of key personnel involved in the IAVI partnership (the IAVI regional office manager, the head of KAVI and the KEMRI-CGMRC IAVI project and the Chair of the HIV Vaccine Sub-Committee) to discuss these preliminary results and receive feedback from them. This was a very useful activity to hear what my interviewees thought. Only one person, a PI, took issue with my results and these were over points of clarification more than anything else. For the most part, my interviewees did not appear too worried or interested in what I had written as other more pressing and practical day-to-day job related priorities took precedence. The exercise was useful however as it allowed me to direct my final discussions in ways I had only partially been able to do during my earlier fieldwork as my ideas where not quite finalised.

During all 4 visits I spent time observing and 'hanging around' IAVI's offices and those of their partner organisations collecting data. The term 'hanging around' (Bernard, 2006; Massey, 1998) is inelegant but very apt to describe the activity that I ended up doing. I would try to arrange at least one interview a day and basically use that as an 'excuse' for being in the office. I was very aware that people were busy and I wanted people to feel I was there for a purpose but at the same time one that legitimated my turning up a bit early or staying on a bit after the meeting to talk to others in the building. Most of the time it did not occur quite as staged as this as, due to the nature of much work and life in East Africa, things never happen on time or as people expect them to and so I legitimately had to 'hang around' as people were late for interviews or I was late arriving and had to wait for a slot to open to reschedule.

During these periods I would directly observe activities in the research organisations, the ministry or other organisation where my interview was, while chatting to receptionists and others in the room/ building. My ability to speak Swahili helped in this respect because it meant that I was able to chat like, and with, everyone I met. In fact, speaking Swahili definitely 'broke the ice' in many places when I turned up initially. I was a 'novelty' for the most part as people in Kenya do not tend to speak Swahili as a first language and certainly do not expect a white foreigner to speak

'safi' or clean Swahili from Tanzania. It provided an opportunity to become more acquainted with support staff and for them to feel like assisting me.

I not only spoke to those involved in the day-to-day activities around the IAVI partnership but also spent time talking and officially interviewing others involved in clinical research and/ or (HIV/AIDS) vaccine development in Kenya but who were positioned outside the IAVI partnership. These discussions provided an opportunity to get a sense of where IAVI and its partner's activities fitted within the wider HIV/AIDS and clinical research arena in Kenya.

I conducted over 50 'official' semi-structured interviews, a proportion of which were in-depth interviews as well as other less formal repeated interviews with key personnel. During my time in the field I kept a field journal and diary. Each of these activities will now be discussed in more detail.

3.2.1 Interviews

55 semi-structured interviews were conducted with Kenya based representatives of the organisations involved in the IAVI partnership or involved in clinical research or vaccine development and the making of related policy in Kenya. In-depth semi-structured interviews were chosen as a data collection mechanism because of their ability to allow for greater depth of explanation and better provide the interviewee's perspective (Bryman, 1988) in ways more structured interviews or surveys are unable.

My interviewees included members of IAVI's New York Office, Regional Office in Nairobi, various staff (principal investigators, lab technicians, nurses, doctors, data managers and community representatives and mobilisers) at the two partner organisations, KAVI and KEMRI-CGMRC, and members of the wider clinical research environment in Kenya (representatives of other research groups) and the policy arena (representatives of the Ministry of Health and the Department of Science and Technology, regional health officials, and members of NGOs and collaborating hospitals). With key personnel within the IAVI partnership more than

one interview was held as well as more informal discussions. These occurred as and when required and as new issues or different angles to existing issues arose as my fieldwork progressed to understand how and why these issues and alternative perspectives were raised.

Topics covered in the interview guide of formal interviews were, in line with my overarching research questions outlined in Chapter One:

- Background information such as details of an organisation's involvement in the partnership and motivation;
- Details of collaborative activities (who, when, where and how) broken down into individual, institutional and macro level details;
- Specific details of capacity building and information transfer and learning processes and;
- Thoughts on how the partnership is progressing and how it impacts what they comprehend as healthcare activities.

The full list of the interviews I held together with a copy of the interview guide sheet that was used are available in Appendix 3.

I also asked some interviewees to diagrammatically present their thoughts on the information, knowledge and learning processes within the partnership. This helped provide a basis for discussion during the interviews and I hoped would be useful during my analysis of the IAVI partnership later. In fact these have not been as useful as I had expected as my PhD developed away from focusing on individual information and knowledge flows towards the wider organisational learning within the IAVI partnership as a whole. This is discussed further below in Section 3.4

3.2.2 Observation

While visiting offices of IAVI and its partner organisations direct observation also occurred of day-to-day activities of the partnership including routine office and laboratory activities together with attendance of appropriate meetings. Field notes were kept as recommended by Lofland (1971 in Bailey, 1978) and contain:

- Detailed descriptions of day-to-day activities;
- Previous activities that are recalled at a later date;
- Ideas and inferences of others and;
- Personal ideas, analysis of situations and impressions.

Field observation provided an opportunity to experience directly the feelings and concerns highlighted in the interviews (Miller and Dingwell, 1997) adding to the internal validity or the extent the results are consistent with the issues studied (Schofield, 1993). In particular, during my observation activities I also conducted informal interviews and general discussions which gathered information regarding:

- An individual's views on their organisation, the IAVI partnership and its context;
- Their explanations for different situations (past and present) and any differences between these accounts and;
- How these differences in explanation are explained (Valentine, 2002).

Field observation allowed me to see things that were not always discussed during interviews and to get a context to issues in the spirit of ethnography. I was able to gain a greater sense of perspective of the organisational mechanisms that would not have – and did not – come out of the interviews I held. This provided a means of getting an understanding of the underlying issues of power and politics that were at play within the collaboration between IAVI and its partners and those outside the partnership but who interacted with it

3.2.3 Document acquisition

Document acquisition was the third mechanism of data collection used. Various relevant project documents were attained during this time. In particular documents relating to:

- The setting up of IAVI;
- The day-to-day running of IAVI including its organisational arrangements with it's partners;
- The funding conditions of IAVI;

- Performance monitoring and evaluation reports and;
- Any other document as appeared relevant.

This mechanism provided an opportunity, along with the feedback from my field report, to verify data and facts reported as well as provide another primary source of data to analyse. Appendix 4 outlines a list of all the Kenyan IAVI partnership related documents I sourced during my fieldwork.

3.2.4 Ethics[21]

This research design has been assessed against the University of Edinburgh's Research and Research Ethics Committee's Ethical Review self-audit process and deemed not to require further ethical review. Formal interviews were conducted only when signed informed consent was received from individuals who participated in these including permission to tape the interview. Direct observation and document acquisition received approval from the relevant authorities. During report writing all data has been aggregated where possible to improve confidentiality and anonymity. The final version of the findings will be placed in the public domain.

3.3 Data analysis

Data analysis used a grounded theory 'Framework' approach (Ritchie and Spencer, 1994). The procedure of this approach is outlined below. Data analysis occurred simultaneously to data collection as per the iterative research process adopted as well as once all data had been collected and collated. Weekly reviews of data took place during my fieldwork and through these I started the compilation of an initial thematic framework or list of important 'concepts' that emerged from the data collected as I started transcribing interviews conducted. I revised the interview guide to focus on specific targeted questions for representatives of partner organisations based on these weekly reviews. As I got better at interviewing (knowing when to ask questions and how to ask them depending on who I was interviewing) and going through the

[21] This sub-section outlines the ethics procedure for conducting the research. My own ethical dilemmas that I encountered are outlined in Section 3.4

interview guide I would also follow leads when they arose during interviews for as long as appeared appropriate.

All interviews were transcribed or, where they were not taped, notes of the interview were typed up. Each of these documents was then coded by organisational type/ name and an interview number put against the document, for example 'KAVI01' or 'POLICY10'. The number was allocated sequentially starting from the first interview transcribed.

I decided to use the framework approach to analyse the data contained in these documents partly because I had used it in previous studies and therefore was familiar with it. However, it also fitted my requirements for an analysis approach. I wanted a mechanism that would allow for a sufficiently analytic-inductive approach whereby the data spoke for itself with limited interference from pre-existing notions and thoughts gained during the data collection process. This approach allowed me to do this because of its formulaic and step-by-step approach. However, at the same time I did not want to loose the nuances within the data that, in the spirit of ethnography, I wanted to concentrate on during my discussion of the data. This approach, in taking a traditional, non-computerised approach to data analysis that requires immersion into the data and constant re-reading of the transcripts and field notes provided me with a way to gain this depth while at the same time logically sort the data into useful categories to make it more manageable.

3.3.1 The 'Framework' approach

The 'Framework' approach (Ritchie and Spencer, 1994) was used to analyse the data collected because it is systematic and has a well-defined procedure. It was also chosen, rather than the full, grounded approach as developed by Glaser and Strauss (1967), because this research is a form of action research for which the 'Framework' approach was specifically developed.

The 'Framework' approach has a five-step process of data analysis. The analysis begins with familiarisation with the data set (the interview transcripts, field notes and

documents collected) followed by the identification of a thematic framework or development of an initial coding system. Indexing of the data collected then takes place using this framework after which the data is charted by a process of abstraction and synthesis that leads to "[searches] for structure rather than a multiplicity of evidence" (Ritchie and Spencer, 1994: 186). Finally, mapping and interpretation occurs. This method emphasises the interaction that occurs between the researcher and the data in order that the nuanced and complex nature of the data is emphasised. As a result, computer analysis of the data was not used in this study to avoid loosing any contextual underpinnings of the research findings.

3.4 Study limitations

During my study I encountered a number of problems that I needed to overcome. These limitations can be divided into two. There were a number of methodology limitations relating to whether I aim to generalise to theory, with regard to reflexivity and the related issue of researcher 'capture'. There were also a number of practical limitations relating to difficulties I encountered in representing the data, collecting the data and in trying to stay focused during the research. I will now discuss each of these limitations and how I have overcome them in more depth.

3.4.1 Methodological limitations

Case study methods, as a qualitative research method, can be criticised with regards to their usefulness in respect to the extent it is possible to generalise to wider populations from them. It has been argued that the case study method can only be used to define a case and not analyse cases or model causal relations being concerned primarily with the analysis of covariance (Gerring, 2004). However, other writers accept that case studies can lead to 'analytic generalisation' or generalisations to theory rather than to populations as in statistical generalisation (Gray, 2004; Robson, 1993; Schofield, 1993; Yin, 1994). However, it has not been my desire to make strict recommendations. It would be impossible to draw exact conclusions and, by

extension, distinguish how widely these can be generalised; whole-scale overarching generalisations being impossible (Glaser, 2000; cited in Patton, 1990: 491). My aim is to provide perspectives rather than truths and context-based extrapolations instead of generalisations. Thus, I have simply highlighted a number of issues regarding the way collaboration and capacity building take place within Kenya around the IAVI partnership and, through an ethnographic/ anthropological rationale, examine how these fit within a wider set of issues and influences.

In using ethnographic based methodology I had hoped that this research would provide an opportunity for greater reflexivity through a stress on dialogue and interaction between the observer and the observed (Burawoy, Burton, et al., 1991). When I developed my methodology I acknowledged that as analysts the researcher brings their own moral ideals and cultural perspective to the research setting (Gellner and Hirsch, 2001) however, through conducting my research in the spirit of ethnography I hoped that the resulting dialogue between the researcher and the key informants would create a shared understanding. I not only hoped that I would be able to more fully understand the local realities but that those I interviewed and interacted with in the course of my research would also gain an understanding of my own research as I aimed to conduct a form of action or dialogical research. Unfortunately, while I gained a great deal of understanding I am not sure to what extent my research created greater understanding by those I interviewed and interacted with in the course of my research. This is evidenced by the lack of discussion that was created by my fieldwork report that I sent to all my interviewees and which received very little feedback or resulted in very little discussion accept that which I made when using the report as a backdrop in my final interviews.

Although I, like others (Nelson and Wright, 1995), would have to acknowledge that it is difficult for me to attain a full understanding of the IAVI partnership in Kenya and completely delete my own perspective from the process, my research has allowed me the chance to understand the relationship between IAVI and the research sites and the attitudes of those involved in this relationship. However, I ended up focusing, as I shall reflect on more below, less on the relationship between IAVI and

various government departments involved in health and innovation than I had wanted and made a conscious decision not to specifically talk to individual trial participants.

The latter was partly the result of the limits of my ethics approval in Kenya (which meant I could not talk to trial participants directly about their role), partly because I was more interested in the partnership process but also related to the fact that IAVI, while interacting with individuals as trial participants, conducted its partnership interactions with them through representatives in the form of peer leaders and Community Advisory Boards (CABs). I was therefore limited to understanding the impact of the relationship on individual community members impacted by the IAVI partnership activities through these mediating agents.

In respect of the former issue of research direction, it would be possible to argue that my research was 'captured' by IAVI and the research process. Much of the thesis is focused around IAVI as the central node within a complex array of different actors. This has implications on the way the story has been told, in particular, the ability of other actors' voices to be heard such as the perspective of the Government of Kenya. This difficulty of 'studying up' where research concerns those in powerful positions has been discussed by others (Mosse and Lewis, 2005). Although I interviewed (sometimes more than once) 11 members of the policy community (mostly staff at different levels of the Ministry of Health and the National Council for Science and Technology) only half agreed to have their interview taped and only three of them agreed to be directly quoted. This has influenced the degree to which 'their story' could be heard. The storyline that becomes dominant in this thesis is in part also related to the skill of IAVI in communicating a certain position and the overall positive spin placed on the clinical trial research activities that take place in terms of IAVI's activities in Kenya. Throughout my study of IAVI, particularly during presentations of my work to various academic and policy audiences, I have been made aware of how positive a picture I paint of IAVI's activities in Kenya. I will discuss the difficulties and implications of this in various chapters of this thesis but it can be seen as a limitation of the study but one which I hope I have overcome. IAVI, as I discuss in Chapter Five, places a strong focus on communications and its global

image. It is very good a presenting a positive image of itself but at the same time the activities it undertakes mean, because there are benefits for those involved, it also appears for the most part a positive relationship for the research organisations and IAVI. In this thesis I have tried to gain some perspective and be more critical by using an ethnographic/ anthropological rationale which focuses on a critical and in-depth analysis of events.

3.4.2 Practical limitations

In conducting the interviews I was constrained by the usual time and access issues that come with interviewing busy people and those in high level management positions. The fact I had to conduct my research at times through the use of mediating agents such as community representatives and peer leaders (to get a view of what trial participants and the surrounding community felt) led to difficulties in writing up regarding representation of the data I collected. In particular, I found my data collection and thus my analysis had the potential to be limited, or rather its later analysis, by the issue of representation. Did I want to claim that people I interviewed where representative of a wider community? However, I had to weigh this against the practical ease of conducting interviews for ensuring the collection of data, particularly through the use of in-depth interviews when participant and long term observations were not possible. In thinking about this issue I concluded that I was not looking for 'representativeness' – I did not need this as I was not intending to make generalisations – but at the same time I also ended up interviewing pretty much everyone who was involved on a day-to-day basis with IAVI's research activities on the ground in Kenya so I was able to ensure a range of views and attitudes would be collected. What I was looking for was to use the interviews to provide a way of highlighting common themes around which there may be a differing of opinion. Thus, in my data analysis I drew out issues (themes) discussed in the interviews by more than one person and that had salience for my discussion on collaboration and capacity. In writing these issues up I have used individual quotes from interviewees to not represent the views of all people who discussed the issue, but to give one version of the 'fragrance' as an illustration.

The second practical limitation concerned data collection and issues of access. These affected my ability to equally observe the activities of KEMRI-CGMRC's IAVI project and KAVI and their relationships with IAVI. I was only able to spend a week at the KEMRI-CGMRC's IAVI project to observe activities. During this time I had to also conduct all the interviews I wanted with KEMRI personnel and other actors involved who were situated outside of KEMRI such as government Ministry of Health personnel. This was due to time constraints of project staff. This impacted on the number of interviews I was able to hold with personnel working on the KEMRI-CGMRC IAVI project. I did conduct a number of phone interviews and email discussions to supplement the information I gathered on the ground during this one week visit. Only having a week to conduct my study, changed the way I conducted my research, the experience I had and therefore the type of data I collected about the KEMRI project. I had a very different research experience with only one week at KEMRI compared to my long period of study of KAVI. Although I was able to spend a longer time conducting ethnographic research around KAVI the quantity and form of this ethnographic work was not as 'intense' as that conducted during my one week stay in Coast Province with the KEMRI project. I think because I only had such a short period of time I had to be more focused and get as much of a 'feel' for the project, its relationships with IAVI, and the impact of the IAVI partnership in this region, as possible. The result is that when I wrote up the research in Chapters Four, Five and Six I found that my data corresponding to the IAVI-KEMRI relationship was much more descriptive and less interview based than that for the IAVI-KAVI relationship.

A third practical issue that particularly affected my research has been around staying focused and ensuring the right balance between letting the data lead and being tied to the research questions I had set myself. An example of this is the collection of data using ethnographic mapping techniques. As outlined above, I wanted initially to conduct ethnographic mapping that would allow interviewees to map the way they saw their relationships with others involved in the IAVI partnership. I conducted 25 of these (an example is available in Appendix 5) however in the end I have mentioned these maps only briefly in Chapter Five. As my research developed my

emphasis on mapping knowledge flows changed. As I developed my conclusions and wrote up my results I still covered the issue of knowledge flows but have addressed it in other ways (focusing on the issue of knowledge exchange). This reflects a wider issue I faced, particularly during data collection, of being taken 'off track' sometimes for days at a time, as I took up and followed issues that arose. Sometimes these have been useful, for example, it was one such 'off track' moment that provided the insight around the disjuncture that is visible between IAVI and its research partners' emphasis on clinical research and healthcare provision. Going 'off track' has also proved invaluable in getting to grips with understanding the discourse and storylines within which IAVI and its partners operate that is the focus of Chapter Six.

3.5 Conclusion

This chapter has outlined the research methods that I chose to use in order to answer the research questions outlined in Chapter One. I have outlined why I chose qualitative methods and in particular my choice of case study research that was conducted in the spirit of ethnography. I have provided an overview of my three data collection mechanisms (interviews, observation and document acquisition) and the process I used to analyse the data. Data collection and analysis is never without its difficulties and therefore I have also provided an overview of some of the main methodological and practical limitations that I have had to overcome in conducting my research.

Chapter Four

Partnership:

He who pays the piper calls the tune?

Jeffery Sachs, the well-known economist, (cited in Freeman, 2003) called new technologies available today such as recombinant drugs, vaccines and information communication technologies potential 'weapons of mass salvation' seeing them as engines of economic growth. Others have highlighted the potential impact of investing in biotechnology on the achievement of the Millennium Development Goals (Singer and Daar, 2001). Unfortunately, in most cases the advances that are required in these areas are aimed at markets that do not have the purchasing power to pay anything like market prices for them. As outlined in Chapter Two, the resulting situation is often discussed in the health policy literature as one of market failure whereby there is not the incentive for private pharmaceutical companies to get involved in providing many of the medicines required for diseases affecting the developing world. PPPs have been put forward as innovative mechanisms to incentivise investment into such medicines. These are seen as fulfilling economic related functions where it becomes 'efficient' to integrate or collaborate; it becomes economically advantageous to form partnerships. In particular, as I outlined in Chapter Two, this is because partnership is seen as creating situations of trust and reciprocity from which social capital or networked collaborative action can take place.

Such perspectives of partnership see the mechanism in positive terms. Criticisms that are put forward around PPPs for global health relate to the governance issues of these partnerships and particularly the lack of consideration given, by these pro-PPP arguments, to the power dimensions of partnership within the context of being the best mechanism for incentivising product development for neglected diseases.

The critiques of global health related PPPs given within the health policy literature are, for the most part, bound up in economic and related social theories put forward to promote the importance of partnership and PPPs. While this theory places an importance on institutional arrangements by stressing the importance, need and usefulness of collaborative activity, often discussion of product development PPPs in the health policy literature have not widely acknowledged the importance of collaboration by studying its institutional arrangements, particularly in terms of PDPs activities in developing countries, in any depth. This is the task I have set myself in this PhD.

In the main, as outlined in Chapter Two, these critiques of health PPPs, although framed within a governance analysis, do not deal in any depth with the day-to-day institutional arrangements that take place within PDPs in developing countries despite collaborative activity being seen as essential for explaining their rise (especially in light of the recent coming together of health policy analysts and innovation specialists and the creation of terms such as 'health innovation').

This chapter, and this thesis more generally, will bring a more normative and explicit focus to the study of partnership to understand the nuances of the institutional relationships bound up within it. As outlined in Chapters Two and Three, I am concerned in this thesis with undertaking a critical analysis of IAVI, a product development PPP, or PDP. Working within the spirit of ethnography in this chapter I examine in detail and in depth the relations that take place in the IAVI partnership in Kenya by considering these issues from the perspective of the ethnography and anthropology of development. This literature has taken a critical and in-depth look at how partnership takes place and issues of participation within partnership (c.f. Baaz, 2005; Cornwall, 2007; Cornwall and Brock, 2005; Crewe and Harrison, 1998; Escobar, 1995; Mosse, 2005; Peters, 2000). This literature acknowledges the existence of different and multiple entities and identities, of different motivations and incentives for getting involved in PDP activities. In so doing, I will look at how these collaborations "become real" to those involved (Latour, 2005; Mosse and Lewis, 2006b: 13).

Taking such a perspective highlights the complexity that exists within the Kenyan IAVI partnership. As I will argue this exposes the difficulty of ensuring true partnership takes place within the IAVI partnership in Kenya. This does not stop efforts towards more effective partnership occurring. My fieldwork highlights the existence, at any one time, of more than one view of how the partnership is working. This is because the collaborative activities within the IAVI partnership differ in their nature depending on where in the partnership attention is focused. The result is that there are examples of bottom-up partnership, top-down partnership and a form of partnership that I term parental.

In realising that the IAVI partnership is not a single definable entity and that the linkages between those involved are extremely dynamic, I will conclude by arguing that there is a need to go beyond value laden notions of 'partnership'. One way of doing this would be to consider IAVI's activities from within the dual framework of innovation systems and anthropology of development thinking. This dual perspective considers the value of PDPs in ways that go beyond simply looking at PDPs such as IAVI in terms of their ability to combat market failure, building on the social theory that is used to promote such partnerships to look at what other functions they have for those involved. I will consider how, from this perspective, the IAVI partnership is more than simply parental, bottom-up or top-down but can in fact be viewed as also being facilitatory, even 'effective' if unequal, in nature. Gains are made by many of those involved and it is not simply a question of 'them' vs. 'us'.

In order to address these issues, I start the chapter with a critical introduction to the arguments of partnership building on that outlined in Chapter Two. This is followed by an overview of my empirical data on the way the IAVI partnership takes place in Kenya. In particular, I outline how it is possible to see the IAVI partnership exhibiting examples of top-down partnership, bottom-up partnership as well as parental style partnership. I discuss the complexity of these multiple identities, how it highlights the difficulties of ensuring true partnership but does not rule out the possibility of ensuring more effective partnership takes place. I conclude with a

discussion on the value of interdisciplinary research using a dual-framework based on thinking from within innovation systems and anthropology.

4.1 What is partnership?

The pro-PPP arguments within the health policy literature that are based on social and economic theory and which stress trust, reciprocity and collaborative action have at their core the idea that different entities within a partnership, different partners, can reap the benefits that they envisaged on entering the collaboration. A frequent definition of a PPP given within the health policy literature is that provided by Buse and Walt which stresses sharing and mutuality within a partnership between public and private entities. They define an international PPP as:

> "a collaborative relationship which transcends national boundaries and brings together at least three parties, among them a corporation (and/or industry association) and an intergovernmental organization, so as to achieve a shared health-creating goal on the basis of a mutually agreed division of labour." (Buse and Walt, 2000a: 550)

Similarly, Widdus (2003a) describes a PPP as a relationship involving at least one private and one public sector player with a mutual sharing (although not necessarily equally) of risk and benefits. The private sector here refers to commercial sector for-profit organisations while the public sector refers to non-profit organisations and government bodies. These definitions build on institutional economics and its critiques that emphasise the social relations involved in collaboration. The emphasis is on each partner gaining what they want from a partnership and a mutuality of agreement to the risks and benefits involved.

Other definitions of partnership, outside of the health policy literature, have also placed the same emphasis on mutuality and common purpose. For example the UN definition of partnership is:

> "…voluntary and collaborative relationships between various parties, both State and non-State, in which all participants agree to work together to achieve a common purpose or undertake a specific task and to share risks and

> responsibilities, resources and benefits." (UN Doc. A/60/214, para. 8 quoted in Martens, 2007: 10)

Partnership, as the UN definition outlines, goes further than collaboration (which is simply the task of working jointly or together) to include a sharing of risks and benefits. Widdus' definition includes the clause that this may not be an equal sharing of risks and benefits however in his definition a partnership is possible because each party involved will have agreed to undertake an unequal sharing of risks and benefits.

Thus even an unequal partnership can still lead to each partner benefiting in ways it expected at the beginning of the partnership negotiations. This notion of agreed benefits is what differentiates between what can be termed 'true' partnerships and those that are simply 'effective' partnerships. A 'true' partnership is based on joint ownership mutuality built on shared responsibility and interests. In a true partnership each partner has the power to determine its share of the risks and results in ways that benefit them. An 'effective' partnership is one in which the goals are attained but in which benefits may not occur as expected because a partner does not have the power to determine these because there is no joint ownership and shared responsibility and interests. Being an effective partnership does not therefore necessarily require an equal relationship between partners, but can at times include situations of coercion or domination. One reason for this is as Fowler puts it, while "[r]esponsibilities can be shared in a partnership; authority seldom can" (Fowler, 1991: 15).

Product development PPPs or PDPs such as IAVI are based on contractual arrangements in order to leverage skills and resources (Kettler and Marjanovic, 2004). This makes it difficult to have characteristics of a 'true' partnership because of the unequal relationship that is inherent under a contract of one partner requiring results from another. IAVI undertakes contractual agreements with research organisations in Kenya just as it does with the pharmaceutical and biotechnology companies in other countries to gain access and develop potential vaccine candidates. But it is because these are contractual arrangements that Nishtar (2004) argues that PPPs such as IAVI should be more than just contractual arrangements between the

public and the private sectors to make them 'true' partnerships built on joint ownership based on shared responsibility and interests.

The difference between 'true' and 'effective' partnership is illustrated by the focus of much of the literature from within the ethnography and anthropology fields that considers international development aid or assistance. For example, Crewe and Harrison (1998) in writing about the way international development, and in particular the way partnerships within international development, have taken place argue that in such cases the notion of partnership is an ideal that will never be possible due to constant "structural inequalities" (Crewe and Harrison, 1998: 77). This is because one partner has more knowledge, resources, skills and so power than another. In this sense the notion of partnership becomes a 'misnomer' (Jack, 2005) as partnership is "never passive" (Baaz, 2005: 9). Any international development partnership of this type, by its very definition, is a situation whereby there is a donor and a recipient.

Partnerships such as IAVI because they relate to collaboration between donors or partners with skills and resources in the 'developed world' and recipients in the 'developing world' enter the realm of international development work. International development work is based on this premise of collaborative assistance. The term 'development' in this context was coined in a now famous speech by Harry Truman in 1949:

> "We must embark on a bold new program for making the benefits of our scientific advances and industrial progress available for the improvement and growth of underdeveloped areas. The old imperialism – exploitation for foreign profit – has no place in our plans. What we envisage is a program of development based on the concepts of democratic fair dealing." (quoted in Estava, 1992: 6)

Those from within the post-modern and post-development schools of thought are highly critical of the way development activities have taken place since 1949 (c.f. Rahnema and Bawtree, 1997; Tucker, 1999). In particular, they are critical of the way notions such as 'partnership' and the related term of 'participation' have been taken up as a means of legitimating development activities. Moreover, these concepts are seen to continue the idea that the developing world needs the assistance

of the developed world and in so doing reiterate the superiority and continued dominance of Western and particularly US hegemony.

Building on this work, it is possible to take a critical reading of the place partnership activities have within the international development arena. This analysis goes beyond discussing the rise of partnership activity within the global health policy arena and developing policy prescriptions for how they ought to take place (c.f. Buse and Harmer, 2004; Buse and Harmer, 2007; Buse and Waxman, 2001; Widdus and White, 2004; Wildridge, Childs, et al., 2004) to consider what actually is happening in developing countries in which PDPs work and whether it is beneficial for those involved. This more critical analysis takes as a starting point the notion that partnership activity has often been considered a natural part of development activities as intervention activities are seen as inseparable from development activities. For example, Jones argues that metaphors such as 'tutelage', 'management' and 'intervention' have been the basis of modern development assistance (Jones, 2004). This has been argued to be particularly the case in science based development activities (Shiva, 1997). Science and development are argued to have been intimately related as a result of much health and agriculture development assistance in colonial times which had scientific research activities as their base (Alvares, 1993). Initially health research in developing countries took place in order to find ways of ensuring the longevity of colonial peoples and their power, few indigenous staff were trained and where they were this often meant training abroad with few, until recently, returning to their country of origin (Trostle, 2000). Science has been associated with progress, value-freedom and objectivity starting from the industrial revolution (Alvares, 1993). At once such a focus places everything else (local knowledge, other forms of progress other than technological or scientific ones) as wrong (Peters, 2000). As such, and as I will outline in more depth in the next chapter, partnerships around health research are increasingly seen in terms of 'research capacity building' activities. In some respects these are only the latest form of old style development interactions.

It is acknowledged that the requirement for and importance placed on 'partnership' as an important activity within development activities has increased since the 1970s (Baaz, 2005; Peters, 2000; Rahnema, 1993). Following independence from colonial powers and the lack of success in halting 'underdevelopment' (the term of choice at the time to explain why some countries where not as economically developed as others) an emphasis was placed on reducing poverty and promoting political independence (Pickard, 2007). In order to achieve this, a focus was initially placed on the need for local participation and empowerment, human-centred development and the meeting of basic needs (Estava, 1992). There was a move away from 'top-down' development that had been occurring (despite Truman's earlier emphasis on democracy and the end of foreign imperialism) with the rise of 'bottom-up' approaches focusing on the role of civil society, social movements and human rights (Peters, 2000; Rahnema, 1993). However, the 1980s brought the return of conservative political attitudes and neoclassical economics, particularly the taking hold of 'neoliberalism' as a political doctrine. These espoused market forces as the way to create development through the creation of economic growth and democracy (Pickard, 2007; Pieterse, 2001). Within this context the partnership concept now relates to how those with the expertise assist those without to economically and politically liberalise and join economic 'assistance' programmes. These partnerships have changed the power dynamics and it is argued the relationship between developing and developed world partners has:

> "hark[ed] back to the 1950s, once again it was the North that set priorities, often unilaterally. Conceptual gains of previous decades were wiped away… For example, the idea that partners in the North and South had to jointly design priorities and strategies to have an impact on a long-term process suddenly disappeared. Now, funds were very often conditioned on recipients taking on particular themes, or readjusting on-going programmes and projects to highlight aspects thought to be important in the North." (Pickard, 2007: 580)

The result is that partnership as a term has taken on 'trans ideological properties' (Cornwall, 2007; Fox, 2007) being used by those from the political left and right. The term 'partnership' and the related notion of 'participation' can be seen as 'buzzwords' that have entered the development lexicon taking on values similar to that of Gallie's 'essentially contested concept' (Cornwall and Brock, 2005). They are simple enough for everyone to recognise but are malleable enough to mean

different things to different people. This gives these terms the power and mileage to be used by those who take them up in ways that benefit them but leave them "beyond reproach" (Cornwall, 2007: 472).

While Pickard in the quote above is referring to more general development partnerships, the change in attitude towards partnerships can be seen in the area of developing country neglected disease health policy as well. The call for PPPs as an incentive mechanism is very much part of this changing attitude towards partnership with the rise of neoliberalism. Rahnema in talking about the changing attitude to partnership within the international development arena highlights how "an expanded concept of participation could help the private sector to be directly involved in the development business" (1993: 120). The rise of PPPs for health such as IAVI is an example of this.

As outlined in Chapter Two, the argument put forward is that PPPs provide a means of bringing in the private sector when they would not otherwise get involved. Within the current neoliberal paradigm it is seen as useful to engage with the private sector. This is because it is where the expertise lies, but also because the private sector is seen to bring efficiency to the public sector. The ways of working within the public and private sector have until now been very different because they have fundamentally different starting points (market vs. social justice). This will inevitably have significant impact on the extent of equality and shared ownership within a partnership.

This supports the critiques of 'true' partnership outlined earlier in this chapter but also shows that the concept of partnership is not new. But how do these various dimensions of partnership play out on the ground in Kenya within what is termed the IAVI partnership? Does IAVI as an international partnership – the way it's usually seen in the health policy literature – differ from how it works on the ground in Kenya? Is the Kenyan IAVI partnership less of a 'true' partnership because it involves interactions between those from unequal starting points in terms of power, resources and skills? Is it still based on equality, commonality of purpose and

mutuality where there is local empowerment (bottom-up collaboration)? Or does it correspond to more critical definitions of partnership and development assistance that express partnership in terms of 'them' and 'us' (Crewe and Harrison, 1998) with an idea that local 'partners' have little power or influence (top-down collaboration) and need foreign expertise (parental collaboration) (Baaz, 2005)?

The value of using an ethnographic rationale to consider these issues, building on the literature from within the anthropology and ethnography of development fields is that it highlights the nuanced realities that are played out in the functioning of partnerships. This highlights that it is not simply a matter of Western or US dominance in the form of a new type of old style international development assistance as suggested by the post-development school (Gardner and Lewis, 2000). Considering the way IAVI works at a national level in Kenya in the spirit of ethnography provides a means of considering these partnerships in a way that the traditional health policy literature has rarely done despite increasing interaction with innovation studies thinking which places an emphasis on the process of collaboration around the concepts of 'health innovation' and 'health research'. I will now explore these questions and issues as they relate to the IAVI partnership in Kenya using evidence from my fieldwork to highlight how the nuances mean that at least three forms of collaboration exist.

4.2 What is the IAVI partnership at country level?

IAVI revolves around a number of collaborations existing within a global PPP entity. At a global level, IAVI can be, and has been defined (Widdus and White, 2004), as a Global Health Partnership and a PPP. At this level, IAVI is made up of a not-for-profit NGO that coordinates an international collaboration made up of private corporations (such as pharmaceutical companies) and intergovernmental organisations (such as the WHO and individual country governments). This is its international identity. IAVI also works in individual countries, increasingly in developing countries, and its activities in these countries lead to the creation of small

IAVI country level partnerships. Both the international and country level partnerships develop as a result of the collaborations or individual, often bi-lateral, partnerships IAVI, the not for profit based out of New York, has with others. These collaborations are either in the form of contractual partnerships as IAVI conducts activities similar to those of a private pharmaceutical company or more loosely formalised 'coalition' or 'consortium' (Fowler, in Penrose, 2000: 244).

As outlined in Chapter One, IAVI organises itself in ways similar to a modern pharmaceutical company acting like a 'Virtual Pharmaceutical Company', as its founder, Seth Berkley, has sometimes called it. IAVI conducts activities similar to those of a pharmaceutical company because it identifies potential vaccine candidates and sponsors their development by outsourcing the development activities to others. While IAVI has moved away from this in some respects (since 2005 it has had its own laboratory conducting applied research) its activities and the IAVI partnership – as this chapter will highlight – are still defined in Kenya in respect of its relations with the public research organisations it contracts to conduct vaccine trial site research, namely KAVI and KEMRI-CGMRC, and how these interact with each other in Kenya.

The collaborations it has with organisations in developing countries do not often include private sector partners so in Kenya one director told me, "I see no private interactions at a country level." The result is that at country level in Kenya the IAVI partnership works as a different form of PPP than at an international level as it lacks a private sector partner. However, it still works as a PPP because the private sector aspect of its activities comes from the private sector based mechanisms in which IAVI, the not-for-profit, works.

My fieldwork in Kenya highlights that IAVI works as a type of PPP at the country level due to an emphasis on using a private sector orientated approach to conducting its activities. In these activities it works not only through formal contractual arrangements with KAVI and KEMRI-CGMRC, but also promotes the development of more loosely formalised coalitions around AIDS vaccine development activities.

In many cases, IAVI plays the central role in establishing and promoting these different forms of collaboration that take place. As I shall highlight below, this means IAVI can be seen as being facilitatory, paternalist or exploitative depending on the perspective taken. For the most part, on analysing the information I received from those I spoke to during my fieldwork the IAVI partnership in Kenya exhibits a 'top-down' style of partnership whereby IAVI determines the course of the partnership particularly as a result of its role as the funder of activities.

This fits with a more general attitude towards the influence of external researchers that has been visible in Kenya in the past with regards scientific research and AIDS vaccine research more specifically. This attitude mirrors some of the arguments discussed above regarding the role of development/ science research assistance. This is well illustrated by the cartoon in Figure 4.1 regarding AIDS vaccine research in Kenya in the mid-1990s. Attitudes regarding the politics of scientific research and the power relations within it (for example who controls funding, intellectual property rights and decision making) were very central to a national debate that occurred as IAVI came into Kenya in the mid 1990s as a funder of research already being carried out by KAVI and its partner, Oxford University. IAVI's role in the partnership at this point was less central, but controversies over the intellectual property rights for the vaccine candidate between University of Oxford and KAVI meant that the partnership was not one of equal power between scientists and funder. The number of actors and the power relations where more nuanced than this. As the cartoon in Figure 4.1 highlights, the way the partnership was perceived within Kenya highlights the myriad of power relationships between many different actors, not simply between the scientists at KAVI and University of Oxford (Geissler and Pool, 2006).

I found that the IAVI partnership in Kenya also exhibits characteristics of a 'bottom-up' partnership where power and decisions are made in a more participatory way with the inclusion of national actors. As I will show below, this characteristic appears to have grown over time as different partners learnt to trust each other and had to rely on each other for information and knowledge. However, despite this, I will argue that the way the IAVI partnership functions on the ground in Kenya is not

an example of a 'true' partnership as there is a lack of more horizontal forms of collaboration based on joint ownership, mutuality and shared agreement

Figure 4.1 Kenyan AIDS vaccine research cartoon
Published by Paul Kelemba, alias Madd, East African Standard, Nairobi (Geissler and Pool, 2006)

Yet the collaborations taking place within Kenya around IAVI's activities have the potential to be defined in terms of an 'effective' partnership due to the facilitatory nature of the collaborative activities whereby all those involved appear to gain although not necessarily equally from their inclusion. I show below in Section 4.4 how the IAVI partnership is an example of great complexity making it impossible to define the partnership as simply top-down, bottom-up or paternalist. The IAVI partnership in Kenya is an example of the traditional international development (scientific research) partnership of donor and recipient but at the same time is more complex than this. I shall now outline evidence of these three types of partnership existing within the IAVI partnership in Kenya. I particularly discuss the relationship between IAVI and the public sector research organisations, KAVI and KEMRI-CGMRC, which is the dominant relationship within the IAVI partnership in Kenya.

Sections 4.3 and 4.4 will then critically discuss these findings. Section 4.3 will discuss how these partnership forms fit with the wider IAVI partnership activities in Kenya.

4.2.1 A bottom-up partnership?

The IAVI partnership in Kenya has characteristics of what can be termed a 'bottom-up' partnership in terms of the way the partnership activities take place and decisions are made. The partners, particularly the scientific partners, on the ground in Kenya, are not only involved in decision making but also take charge of certain aspects of the decision making process. This is visible in a number of ways. Firstly, IAVI plays a supporting role towards both scientific partners, KAVI and KEMRI-CGMRC. Both research centres were in existence before IAVI came into Kenya and are valued as important research sites in their own right. Secondly, the overall scientific direction of IAVI has been influenced by the scientific partners in Kenya. There are times when the scientific partners have identified areas of research and taken them forward. Finally, IAVI is not involved on a day-to-day basis with decision making at the research sites. However, this participatory process is complicated by the fact that both parties involved, IAVI and the research centres, KAVI and KEMRI-CGMRC, need each other. The research centres require IAVI's funding and resources that it can provide while IAVI needs the community level expertise that the scientific partners have. As a result the relationship is defined by two-way relations and not simply by one way, bottom-up participation. I shall now discuss these issues with examples.

In 2006 a new addition was added to IAVI's KEMRI-CGMRC trial site based out of Kilifi in Coast province, Kenya; described to me by its Project Manager as the 'last child in the IAVI family'. On March 28th 2006 the Comprehensive Care and Research Clinic (CCRC) was officially opened by IAVI's CEO, Dr. Seth Berkley, to provide "collaborative HIV care and research in support of the Kilifi Community". This centre is the latest in a series of facilities that have been developed at the Kilifi District Hospital (KDH) through collaborative agreements with donor funding agencies, at times through the KEMRI-CGMRC research centre that is also based in

Kilifi. In this case, the CCRC is the result of collaborative efforts between the KDH, as the care provider, together with a number of supporting groups. These groups are IAVI, who financed the building of the facility and maintenance of the laboratory, as well as KEMRI-CGMRC, PEPFAR (the US President's Emergency Fund for AIDS Relief) and the US Center for Disease Control (CDC) which provide ARVs and general funding for the day-to-day activities.

The CCRC consists of a waiting area including a play area for children, consulting rooms, sample taking rooms, a data room, a pharmacy (at the time of my visit this was not being used as there was no pharmacist employed to own it) and a laboratory. The CCRC is run by the hospital and all medical staff are hospital employees. Lab staff are paid by the project budgets of IAVI and Wellcome Trust. The lab has been renovated, resourced and is maintained through efforts from both IAVI as well as the Wellcome Trust who work with KEMRI in Kilifi.

In the case of the CCRC, IAVI plays a supporting role; it is not actually involved in care provision itself but has provided the facilities and supports their maintenance. This is part of its provision of support to KEMRI to undertake AIDS vaccine feasibility research activities. IAVI's contract with KEMRI-CGMRC means it provides financial and technical support to enable KEMRI-CGMRC to develop an IAVI project to build up an AIDS vaccine research trial site.

Along with the CCRC, the IAVI KEMRI-CGMRC project has two other locations. These are a community HIV centre within the KEMRI compound in Kilifi next door to the KDH, and a drop-in centre in collaboration with the University of Washington in Mtwapa, a coastal town just outside Mombasa. There were a total of 34 staff (including support staff such as cleaners, drivers and gardeners) working in these three sites paid for with IAVI funding when I conducted my fieldwork.

When the KEMRI-CGMRC IAVI project was established the starting point was the Community HIV Centre. The first research study looked at normal values, trying to find a baseline of laboratory and haematology criteria which future vaccine trials can

use (Protocol D).[22] This centre operates just within the gates of the KEMRI-CGMRC compound in Kilifi as a VCT centre. From the cohort of VCT patients, volunteers are recruited to Protocol D whereby they visit the centre twice. In the first visit, volunteers are enrolled into the study and receive VCT. In their second visit they receive their VCT results. If these are HIV negative they have blood samples taken. The blood samples are analysed in the lab and the values found go towards the study findings.

The third site is the drop-in centre in Mtwapa particularly aimed at a high-risk cohort (sex workers and men who have sex with men or MSM). A collaborative project with a University of Washington based team who are conducting research on ARVs, the project was the idea of the KEMRI-CGMRC IAVI Project Manager. In this instance the research centre has influenced the direction of scientific research. He saw the potential of being able to conduct research (Protocol B) into HIV incidence within high-risk cohorts while being able to ensure care provision for those who sero-convert (become HIV positive) during the study. It also provides an opportunity for the research site to increase the cohort for conducting Protocol C, a study that looks at recent infection, allowing those that sero-converted within Protocol B to move into another study, Protocol C. The KEMRI-CGMRC IAVI Project Manager explained to me, that while IAVI was the funder and originator of two of the three studies (Protocols C and D), the high risk cohort was his own concept. He saw how the research IAVI was already sponsoring at a trial site in Nairobi to conduct Protocol B could be expanded to his trial site.

Thus when discussing a research study's protocol design process there is agreement within the research organisations in Kenya that they have a say in protocol design and as was highlighted earlier, if someone comes up with a good research idea, it can be taken forward:

> "when we have the international AIDS vaccine meetings, we could meet and if somebody has a thought about a new study, then it's shared there and then a draft is circulated and people… So somebody drafts it, a lot of input comes back and forth from different people, before we finally develop the final

[22] A table of the protocols mentioned in this section is outlined in Figure 1.1 in Chapter One.

> protocol and then submit it to the ethics and so on. It's a lot of, there is a lot of input from both sides." [KAVI18]

As the above overview of the KEMRI-CGMRC IAVI project outlines, IAVI is not involved on a day-to-day level in decision-making or performance of activities at project trial sites. Nor is it necessarily the one that initiates new research study ideas. IAVI needs the research organisation's involvement in order that it can conduct clinical trials and feasibility research while the research organisation require money and assistance in order to conduct their activities effectively and efficiently because KEMRI-CGMRC in Kilifi historically has not been involved in HIV prevention or treatment research. Thus there is a two-way relationship between IAVI and its scientific partners in Kenya.

This two-way relationship is exemplified by KEMRI-CGMRC's relationship with IAVI. The KEMRI-CGMRC based in Kilifi has traditionally focused on malaria research and in particular paediatric related malaria research which has mainly been supported by funding from the UK's Wellcome Trust. KEMRI is the country's national medical research institute, initiated by an Act of Parliament in 1979 and which initially came under the governance of the National Council of Science and Technology. It has now become an independent entity with direct budget support through the Ministry of Health. Due to competition within government departments for scarce resources and in order to benefit from capacity building opportunities afforded, KEMRI has developed a number of long standing research collaborations with international research organisations such as the Wellcome Trust. If the CGMRC was to branch out into HIV prevention research, a similar form of research collaboration was necessary. Working with IAVI provided such a mechanism. However, the collaboration was not initiated by KEMRI but the result of IAVI's desire to have a second research organisation working with it in Kenya which saw IAVI's Seth Berkley actively searching out the Project Manager while he was working in Ethiopia to develop the research project.

A similar situation takes place in terms of IAVI's relationship with KAVI, the Nairobi based research organisation. Following a history of working on HIV/AIDS

science by the Department of Microbiology at the University of Nairobi and in particular working with the University of Oxford and the UK's MRC to develop the first HIV vaccine candidate (DNA-MVA), KAVI was borne out of a "tri-partite agreement between the University of Nairobi, IAVI and MRC Oxford" [KAVI18] in 1999. Following an unsuccessful first vaccine trial (the vaccine was deemed unsuccessful, however, the trial itself organisationally was a success) negotiations followed between IAVI and the University of Nairobi to continue activities in AIDS vaccine trial research. IAVI saw the potential that this first experience had provided in moving beyond simply financing trials and become more involved in the actual activities to find promising vaccine candidates and creating a permanent trial site in Kenya to test the vaccine candidates. At the same time, personnel at the University of Nairobi who had been involved in the initial trial were keen to develop a full scale research group within the Department of Microbiology. Thus again, as with KEMRI, the relationship KAVI has with IAVI is a two-way relationship.

The result of the KAVI-IAVI collaboration is that KAVI has:

> "grown from a staff of three in 1998 to a staff of over 45. Yes, we are now occupying two floors, the labs are fully equipped and quite a bit of the cellular immunology is being done right here. So I think even without me telling you, you can actually see that the collaboration has been successful." [KAVI2]

KAVI is based within the Department of Microbiology at the University of Nairobi. This was the site of the initial trial for the DNA-MVA vaccine. The site has now conducted five clinical trials (both Phase I and Phase II) and over 10 feasibility studies. A second research site was added in 2004 in Kangemi, a low socio-economic neighbourhood of Nairobi, where a focus is placed on developing and working with a high-risk cohort (sex workers and MSM). This site is located within the compound of the Nairobi City Council Health Clinic in Kangemi operating out of container offices to one side of the clinic buildings.

Day-to-day activity within KAVI is managed by the Project Coordinator who at the time of my fieldwork was a Professor in Microbiology who had been one of the initial founders of KAVI. Decisions as to how the KAVI and Kangemi sites are organised are made by him and his team of Principal Investigators (PIs). This team

makes decisions with regards to how the clinics are run, who is on duty, how community mobilisation activities are run including how peer leaders and community advisory boards work.

The result is, as one IAVI staff member pointed out to me, a delineation of authority between what IAVI is in charge of on a day-to-day basis and what its scientific partners in Kenya are. In particular IAVI realises it does not have expertise in all areas being aware that its partners can provide this support. Thus as an IAVI staff member from within the CRP told me:

> "The way I always look at it is, you have the trial site community and everything that happens in that trial site community falls under the purview of the scientific partner. So, if KAVI, I use KAVI always as an example because they're sitting next door, I'm not picking on them… I wouldn't just go to KAVI and say, evaluate your peer leaders… I know what's going on in terms of their peer leaders, but I have no day-to-day function in terms of interacting with the peer leaders, that really is KAVI." [IAVI6; emphasis added]

While KAVI is in-charge of the scientific research or clinical trial activities that they undertake everyday, this IAVI staff member did acknowledge a role for IAVI outside the research sites: "…IAVI has a role to play in terms of education and awareness building but not as it directly relates to recruitment or a specific vaccine or feasibility study" [IAVI6]. She did clarify that this was in terms of what happens outside of the trial sites external to surrounding communities as these fell under the purview of the scientific partner:

> "In much the same way as IAVI wouldn't micro-manage every single test that's being done in the lab, we wouldn't micro-manage what every community seminar that's taking place, at that community" [IAVI6]

There was understanding within IAVI from four of the six main staff members I spoke to in Nairobi, that their scientific partners have expertise in certain areas, particularly in terms of understanding the communities in which they work being the focal point for local communities and healthcare providers to find out AIDS vaccine research information. For example, the same IAVI staff member mentioned above stressed earlier in our discussion:

> "I think that going into a trial site, the scientific partners tend to hire people with an awful lot of training, an awful lot of know-how in terms of the

> community mobilisation much more than myself or other people in my department have in many respects. I was just reading a profile that our Amsterdam office sent us of one of the community mobilisers in Kangemi and she came with not only a wealth of experience but she knew the Kangemi community like the back of her hand and I think that there's not much we can add to that kind of experience and that kind of knowledge, maybe some of the content pieces for sure but I think its much harder to get the community perspective." [IAVI6; emphasis added]

The role of IAVI is to assist in ensuring wider community awareness and understanding of the IAVI partnership activities, as a way to "de-stigmatize" the communities in which clinical research takes place. Yet at the same time to ensure IAVI can "engage" with the communities around the trial sites and the scientific partners' role remains important as they have the processes and specific materials required: "Maybe we can at times be a bit of a process to de-stigmatize a community but in terms of knowing the community and how to engage them its process and materials specific." [IAVI6]. As will be argued in Section 4.2.3, this has led to some discussion as to the way IAVI conducts its advocacy work in developing countries and how it uses the work of the scientific partners and their community engagement activities around their trial sites to legitimate its activities.

Thus, KAVI and KEMRI manage their day-to-day activities at the research sites and are the focal point for more locally based collaborative activities with local healthcare providers and the communities in which they work. They have some shared involvement in the protocol design process and deem what support they require from IAVI, particularly for their community advocacy activities. However this section has highlighted a more negotiated situation than one which is 'bottom-up' in initiation whereby authority is only being generated from the grassroots. The partnerships are the combination of a need to collaborate on the part of both parties. For example, this section has highlighted how KAVI and KEMRI-CGMRC have benefited from resources and funding from IAVI while IAVI has benefited from its own need for trial sites in which to trial the vaccine candidates it identifies. This section has also raised an issue, which I shall discuss in Section 4.4, of the role of collaboration's 'bottom-up' activities as a legitimating tool for IAVI. As a result, the collaboration is extremely nuanced and not simply defined as a 'bottom-up'

approach. As will be discussed in more depth below, and despite one person in IAVI openly voicing a concern that the PIs can be almost too powerful at times being able to say "this is what I want", there is an issue that this collaboration is only bottom up to the degree that such autonomy is 'given' to the research organisations by IAVI.

4.2.2 A top-down partnership?

The idea that IAVI dominates the relationship between the research organisations and IAVI in Kenya is seen to have increased over time as the size of IAVI and its operations have developed. IAVI is often seen as the sponsor and funder of research rather than an equal partner. The result is that IAVI is the overall authority within the partnership because it initiates most of the work. This has influenced the way people identify themselves. For example a number of people I spoke to described themselves and their organisation as IAVI and not as either KEMRI-CGMRC or KAVI. The main reason for the dominance of IAVI is due to its financial control. It is seen as the buyer of services from vendors, the research organisations. The result is predominately a linear reporting and information transfer system that is top-down from IAVI to KAVI and KEMRI-CGMRC project staff and on to lower staff and external partners such as local community representatives. However, this is complicated by the existence of two centres of IAVI control: IAVI New York and IAVI's regional office in Nairobi. The lack of control the research organisation's have on influencing decisions is exacerbated further by the lack of interaction that occurs between the research organisations KAVI and KEMRI-CGMRC. These issues will now be discussed on more depth.

The way the research organisations have interacted with IAVI, particularly KAVI as the longest research partner in Kenya, has changed over time with less engaged decision making taking place as time has passed. This was seen as related to the way IAVI has grown in size and operations reducing the degree of personal engagement with Dr. Seth Berkley. The KAVI-IAVI collaboration started as a result of direct interaction between the Project Coordinator and Dr. Seth Berkley. The interaction between these personalities has now reduced. The KAVI Project Coordinator in 2006 told me that in the beginning before the regional office, there had been a great

deal of close consultation and joint activities between KAVI and IAVI. Since the partnership has grown in size, he was now less involved in decision making that occurred in New York in relation to the way IAVI as a whole worked:

> "It was very personal at one time. We were very close but of course now with the expansion we see them less often but still I think we have mutual respect of each other…
> …" As I have said the only thing — is that they have changed the personnel so that they are not as close as we used to be. It's grown so big in such a short time although that has strengthened it. They [IAVI] are no longer for example… I no longer go to the meetings in New York and don't participate in the planning at all. And they have someone who attends it on our behalf now. And that is – I find that unacceptable. It's a ridiculous idea that we instead of representing ourselves at all forums both scientific and administrative we have somebody who's supposed to." [KAVI1; emphasis added]

He felt that, as a result, they no longer had much say in the direction research took:

> "…We are no longer involved in deciding on a protocol that we participate in…They just come and tell us what has been said, what has been agreed on, when it's going to take place, and whether it's for us. I don't think they involve us very much." [KAVI1; emphasis added]

The idea that there has been a change in the way the collaboration occurs and the power that the research organisations have within the collaboration was echoed by all members of the senior management at the time in KAVI. The issues they raised are exemplified by an interview I had with one of the PIs. He told me that there was a one-way relationship between IAVI and KAVI whereby they (KAVI) provided all the information in the form of data, quarterly reports, audits and through regular monitoring of their activities by IAVI and its consultants. He felt that IAVI was not a collaborator but a sponsor who pays for results. He contrasted the type of relationship they have with IAVI to other partnerships he had been involved in as part of the Department of Microbiology. He argued that when compared together they did not have a partnership with IAVI because they were not on an equal footing with IAVI:

> "…[IAVI] it is more of a sponsor. What I see of a collaborator because we have collaborated before with the… with Manitoba, a Canadian University in Canada, is we write proposals together and look for funding together, isn't it? And run research together. All right? But this one is where IAVI…[i]t says KAVI is a good site we can sponsor them too to do this vaccine. So I see the larger part of it as a sponsor. It may be a bit of a collaborator in the terms of

> the… there is some research not necessarily vaccine research, like now what we are doing in Kangemi, that we can now refer to that as collaboration as we are looking at research in the raw sense of research but to a bigger extent the goal of IAVI is actually to sponsor vaccine trials internationally." [KAVI2]

Similarly there was a feeling within the KEMRI project held by just over half of the 26 people I interviewed that although the collaboration had occurred to achieve mutual gains, the relationship was unequally skewed in the direction of IAVI and that the organisation's (KEMRI-CGMRC) staff had to prove that they were worthy of the collaboration. For example:

> "We knew IAVI as our sponsor, but we were not working very closely with them as we are today, but with time we have grown very close, and that tells me that we are actually growing. By then we had not established ourselves, we had to prove that we can have a project, an HIV project, but after the first feasibility study, which proved that we can actually go to our next second step then IAVI came out strongly, and the relationship has grown very strong. In fact we have to see them very often, coming over to see what we are doing." [Kilifi13]

As such I received the impression overwhelmingly from all those I talked to within the research organisations and even within the wider policy environment that IAVI was the 'sponsor' or 'funder' of the projects and as such had the overall authority for the activities that took place at the trial sites: he who pays the piper plays the tune. IAVI was often seen as the main initiator of protocols undertaken by KAVI and "the funder and originator of two of the three studies" undertaken by KEMRI-CGMRC. There was acknowledgement of some ability to influence the research agenda by the research organisations. This is acknowledged in Section 4.2.1 which highlighted how KEMRI's third study looking at a high risk cohort had been initiated as a result of a proposal from KEMRI-CGMRC to IAVI.

The dominance of IAVI within the collaboration has influenced the identity of staff within the research organisations. Although KAVI had a more distinct independent identity as 'KAVI' I did receive a number of comments along the lines of "what is the difference between IAVI and KAVI, its almost one thing". This was however most pronounced within the KEMRI-CGMRC project where just under half of those interviewed talked of being IAVI staff or words to that effect. Those working in

KEMRI-CGMRC on IAVI projects identified themselves with IAVI despite being paid staff with KEMRI. When asked about their interaction with IAVI I was told on frequent occasions that "they were IAVI". This was particularly the case in the Mtwapa research site. Staffed by KEMRI-CGMRC members, this site advertised itself on its sign board outside the research site compound as the IAVI-UW (University of Washington) project.

This initially appears strange as the IAVI project at KEMRI-CGMRC has more ability to survive without IAVI funding due to KEMRI's long history as Kenya's premier research institute. Its dependence on IAVI should therefore be less. KEMRI-CGMRC has had a long standing relationship with the Wellcome Trust that provides funding and capacity building activities while the KDH has numerous other collaborations (for example with CDC and Danida to name just two). Add to this KEMRI's long standing independent history as a research centre and it is strange to think that KEMRI-CGMRC staff should identify themselves with IAVI in a way that KAVI staff do not. There is however, in both, a desire by staff to identify themselves as project specific staff i.e. as KAVI staff rather than University of Nairobi staff or IAVI staff rather than KEMRI-CGMRC staff. In the KEMRI-CGMRC instance this is because staff relate to where their salaries are coming from. Plus KEMRI has often suffixed its name to that of the funder so people talk of KEMRI-Wellcome or KEMRI-CDC or KEMRI-Walter Reed. These are projects within KEMRI but which are funded by external donors whose name KEMRI is suffixed with.

This may relate to the fact that both KEMRI-CGMRC and KAVI are contractually bound to IAVI. They are not equal partnerships in the financial sense (even if they might be intellectually, and even here – as the next chapter will consider – this is debated). IAVI has contracted KEMRI-CGMRC and KAVI to perform certain activities for it. Through these contracts IAVI currently pays for everything related to the funding of both projects. Although KEMRI-CGMRC has some further collaborations as part of the IAVI project (i.e. in terms of the CCRC and with UW in Mtwapa) the project staff, equipment and facilities for the project are paid for by IAVI. At present for KEMRI-CGMRC this is for the life time of the protocols only.

KAVI, on the other hand, has entered into a Master Site Agreement whereby IAVI finances the research organisation in its totality for a period of five years during which time KAVI conducts protocols and studies for them. As such, the partnerships are not equal and never will be. The implications of which is that the governance of this collaboration will be of a linear and top-down variety as IAVI is the buyer of services rendered from the research organisations. As one person put it to me, the University of Nairobi is "almost like a vendor".

This linear and top-down governance structure is found to feed through from IAVI to the research organisations and onwards through to the partners on the ground in their trial sites that the research organisations work with. Operational and informal collaboration is dominated by day-to-day interaction between IAVI staff and the PIs at the research sites. However, less interaction occurs between IAVI staff and 'lower' staff at sites. The research sites work using a linear information transfer system whereby information is relayed as necessary down the management structure. Day-to-day information that is transferred without a formal structure includes email and phone call queries about how to conduct a specific aspect of a protocol or discussions regarding a particular lab test or community advocacy tool.

At the same time, this dominance of IAVI was also highlighted in my discussions with policy level personnel and those involved in other AIDS research projects external to the IAVI partnership. For example all ministerial staff I spoke to strongly stressed the dominance of IAVI's role in ensuring new policy guidelines were developed and the correct regulatory structure was put in place. A similar issue was raised by one other external stakeholder I talked to and who is involved in the AIDS vaccine research activities. A couple of ministerial staff even went as far, although not on the record, to question the degree of independence that the HIV vaccine sub-committee within the Ministry of Health had due to IAVI's involvement in its set-up and continued financial and administrative support. This was echoed in discussions I had with a programme head of another research organisation working on another AIDS vaccine research project who asked me to clarify what role IAVI played on the

sub-committee and its relationship with KEMRI as often IAVI was said to represent KEMRI-CGMRC at meetings.

This appearance of linear top-down governance is also reflected in the relationship between the research organisations and their community partners through the community advisory boards (CABs). When I sat in on a KAVI Kenyatta National Hospital (KNH) CAB meeting I was aware that on several instances the community mobiliser who was there representing KAVI 'demanded' information as though the CAB had little choice in the matter. It felt like the CAB were pawns to KAVI and also therefore to IAVI with KAVI in many respects just the 'messenger'. I received the impression that the CAB's independence was limited. This felt particularly the case when it appeared that the community mobiliser had put something onto the agenda, had perhaps prepared the agenda even, because she needed information to report back to IAVI about CAB activities. In a second instance the CAB were told that three of them were expected to attend a CAB exchange visit meeting organised by IAVI. When I talked to the CAB chair later during my visit to KAVI and asked about the drawing up of work plans for CAB activities her answer exemplified this linear power structure from IAVI to KAVI to CAB:

> "… there are occasions when as a CAB we work out work plans and intentions (this is what we would like to do within the year). And on presenting our work plan its like money hasn't come from IAVI or these are administrative issues so I guess that the relationship that's here. IAVI is the financer and it approves this or doesn't approve and therefore you can move on with this or not move on with this financially. So, because without finances we cannot also move with our work plans and we can't move with our work plans unless KAVI approves them and KAVI can't approve unless IAVI approves. So, from my understanding, that's the relationship." [KAVI20; emphasis added]

This linear relationship is complicated by the existence of two centres of IAVI control between IAVI's headquarters in New York and IAVI's regional office in Nairobi. Over a quarter of my interviewees (mostly those within IAVI but also senior staff within the research organisations) highlighted confusion between the relationship of regional office staff, IAVI New York and the research organisations. This is exemplified by this quote from an IAVI regional office staff member:

> "With regards to government and the community the flow of information is through us. Through the regional office to IAVI headquarters. With regards to

> the scientists who are doing this specific research, we have to struggle to be part of this communication because many times they communicate directly – they don't need us – because their funding still comes directly from New York." [IAVI1]

An example of this is in terms of lab data which is sent to data management companies in either the US or South Africa. Any queries regarding the data tend to result in discussions between data managers at the research organisations in Kenya and the data management companies or IAVI's data manager in New York and do not involve the IAVI regional office staff. The same is sometimes true of discussions on protocols that can occur between a Kenyan PI on a project and the New York based project manager for a protocol. This creates a situation where there are unclear roles between the offices. As one KAVI staff member told me:

> "Well, it – as I said – it was very good initially as a collaborative organisation. As I said they worked very close with us and the other partners who are involved in the regional studies and so on and so on. But as it has expanded they have grown more people and as anything that expands that rapid it has its own problems. At times there are no clear roles about various members of IAVI those both here and the New York office also, so there is sometimes overlap and duplication of efforts." [KAVI1]

This linear relationship is further exacerbated by the lack of interaction between the research organisations, KAVI and KEMRI-CGMRC, and other partners on the ground to discuss AIDS vaccine development activities and issues. There is some limited interaction between the geographically split research sites (KAVI and KEMRI-CGMRC). I found examples of interaction between the research labs at these different sites in Kenya and with labs in other countries but often IAVI acts as a 'go-between' in these activities. Thus, when I asked a member of IAVI's regional office if the research sites work independently or if there is regular communication I was told that:

> "they work independently of each other so we're basically the link. So a lot of the information that would be going out will be going out to the sites – it's going to all Principal Investigators or to all Lab Managers or whatever. Um, so I guess we are the link." [IAVI2]

I did not find any evidence to contradict this statement from research organisation staff members. As I outline in more depth in the next chapter the relationships

involved in knowledge exchange between research organisations tends to be mediated by IAVI.

There is, however, a good deal of interaction between sites within the different research centres e.g. between KAVI staff at Kenyatta National Hospital and Kangemi and between KEMRI CGMRC staff in Kilifi and in Mtwapa. This includes staff moving and working between the sites, intra-site equipment loans and joint supervision activities as described by a nurse in KAVI:

> "I've not been to Kilifi but Kangemi yes. Because Kangemi, we liaise a lot. Because even before Kangemi was started… another thing I forgot to tell you I also make sure that the newly employed nurse counsellors are well orientated and that they know what we do in our vaccine research. So most of the nurses who are in Kangemi pass through here for orientation before they could go to Kangemi. And even before they started Kangemi we ordered most of Kangemi's drugs, equipment and all that, the stationary, they were getting it through here. And even there are occasions when we do VCT for clients we find that we don't have enough reagents so I communicate with those in charge at Kangemi and even when they don't have enough of any of the required equipment or drugs they liaise with us and we give them. So we communicate a lot. And even we get supervision, we do it jointly, because from here, participating or acting participating counsellors there are only two of us. We needed to form a group of about 10 so the majority are at Kangemi so we meet every Saturday, every other Saturday, as a group to share our clientele work and support each other when it comes to counselling issues." [KAVI10]

4.2.3 A parental partnership?

The previous two sub-sections have highlighted how IAVI has characteristics of both 'bottom-up' and 'top-down' partnership. Neither of these forms of partnership are however mutually exclusive, they are heavily connected and intertwined. This is because both sides of the partnership between the research organisations, KAVI and KEMRI-CGMRC, and IAVI, need each other. This mutual need is related to an overarching third type of partnership form that is present but is recognised and discussed in different ways by different members of the partnership, as I shall outline below, in both positive and negative terms. However, at all times these discussions highlight unequal power relations. This is what I have termed the 'parental' partnership.

The idea of parental, potentially even paternal, partnership brings out the unequal power relations that dominate and the similarities the IAVI partnership has with previous scientific research partnerships and international development assistance projects of the past more generally. As described earlier in this chapter such partnerships can be seen in 'donor' vs. 'recipient' terms whereby expertise and resources are provided for the 'underdeveloped' partner by a 'paternalist' donor. Baaz (2005) discusses the 'paternalism of partnership' in relation to development aid's recycling of images from colonial history and the creation of new post-colonial versions. She argues that these arise out of the discourse of development aid and how that discourse takes place. Such considerations may explain why IAVI was considered in paternal terms by those I spoke to. Similarly, it is important to note that elements of Kenyan society have been argued to be paternalistic, particularly based around patron-client relations (Haugerud, 1995). This is another factor that may impact the way Kenyan actors involved within IAVI, its partners and, AIDS vaccine research more generally, may consider IAVI's role and activities in a paternal manner.

The partnership between IAVI and the two research organisations in Kenya, KAVI and KEMRI-CGMRC, can be seen as a parental form of collaboration, whereby IAVI acts as the guardian, advisor and benefactor to the research organisations of KAVI and KEMRI-CGMRC. This relationship can be seen as that of a domineering master or it can be seen as a nurturing mother. In recognising that each side needs the other, IAVI and its partner research organisations in Kenya, may have a 'top-down' partnership but they also have a partnership built on the role that each can bring to the other. Most specifically the relationship is built on what IAVI (as the resourced partner) can bring or give to KAVI and KEMRI-CGMRC. For those within IAVI the result is the feeling that they play a nurturing role in the partnership. However, for 24 of those I spoke to within the research organisations and external stakeholders including policy actors (around one third of all interviewees) the attitude is more negative, of one in which IAVI is seen as dominant. The reality is the existence of both positive and negative connotations of such a partnership but at all times there are unequal power relations. I shall now outline these points further.

The idea that IAVI can play a 'nurturing' role through its partnership with the research organisations of KAVI and KEMRI-CGMRC was brought out particularly in discussions with IAVI staff. As will be expanded upon in the next chapter there was a feeling initially that there was not the capacity in Kenya to conduct clinical trial research prior to IAVI's involvement and that the research organisations were young and immature in their skills and infrastructure base (although they did have strong community understanding and linkages); that they needed nurturing and bringing on. As one IAVI staff member told me:

> "You can't just walk in and do a trial. The staff have to have lots of training and establish all the procedures etc. Somebody else could have done it….any other group… All the other groups working in the developing world would have to have the same, you know, process. There is no where in the world that if the person hasn't done a clinical trial before you send them the protocol and say, 'could you let me know when you have the data'. I mean, it doesn't work that way because good clinical practice, as you know, there are requirements and there are the requirements of the investigator but there are also the requirements of the sponsor. So basically we are just doing the same as we would in any country, we are going in and making sure you are covering all your responsibilities to conduct the research." [IAVI2; emphasis added]

Thus a colleague of hers within the CRP department argued that the role of IAVI was therefore to support and provide capacity building assistance when it was required in order to strengthen not only the capacity of staff to conduct their activities but also for site ownership. There was an idea that IAVI should enable the research sites to become independent and stronger players within the partnership and within the clinical research arena more generally:

> "What we do is that we support their activities. As I said, the sites have structures and they need to feel the ownership of the programme and every time they need our support they come to us in terms of whether they need capacity building or some kind of communications with the community, or anything they need to educate the community about, they come to us and we can organise trainings for that. But we want the ownership of the activities to be done by the sites so that we don't be seen as IAVI but the sites are the contact person." [IAVI3; emphasis added]

IAVI was seen as having not only a role in building the capacity of the research organisations but also, and in doing so, to bring a degree of systemisation currently lacking to clinical research in Kenya. This was seen as important for building the

capacity of sites to manage and take a lead in clinical research activities. For example, to quote one IAVI staff member:

> "When you asked in terms of what IAVI can bring to the table, I mentioned it in passing but I do really see it as important, I think that IAVI really can bring a degree of operationalising and systematising to the kinds of activities that take place at the sites. I think that, for the most part there would be broad activities but they don't exist in the framework with attracting back to objective, just again systemisation of how they translate. It's different for all sites, some sites really are stronger in terms of this than others, but I do think that that is something that IAVI can bring to the table and support the sites with." [IAVI6; emphasis added]

The importance IAVI places on local leadership and expertise was highlighted in the first independent review of IAVI conducted in 2003 which stressed the importance of IAVI not appearing as a Western or US organisation intent on imposing its own values and demands on developing countries (Solnick, Ajayi, et al., 2003).

Yet for many on the receiving end of the partnership activities (staff within the research organisations and the partners of the research organisations in the local communities where they work) IAVI can come across as the domineering master. Such sentiments are visible in the quotes, in Section 4.2.2, above by the Project Coordinator of KAVI when he is discussing the changing relationship over time between IAVI and KAVI and more particularly by the PI in KAVI who outlines the one way process of information gathering. These quotes highlight the feeling that IAVI dominates the decision making process and determines what studies are undertaken and what activities will be carried out. Similarly discussions of the partnership by the CAB Chair also highlight such sentiments when she discussed how IAVI was the ultimate decision maker when it came to the activities of the CAB, including deciding when capacity building activities such as CAB exchange visits were to take place (although, when I observed the meeting, I found that the CAB members had called for such visits to take place in the past).

The recognition that IAVI finds, facilitates and coordinates the studies led a number of people to tell me that they saw IAVI as the "Master" and the "Mother support" as they were "our overall bosses". This was related to the fact that IAVI was the funder

of the research making KAVI and KEMRI-CGMRC the 'vendors' and service providers. However, despite this, there is recognition within the research organisations that IAVI provides much needed resources and builds skill within the research organisations. There is acknowledgement that this relationship is beneficial for those involved.

This leads to recognition that while the relationship between IAVI and the research organisations may not be equal, those within the research organisations do themselves gain. There is also some recognition within the research organisations that they do need 'nurturing' and that they benefit from the collaboration with IAVI. This is exemplified, as outlined earlier in this chapter, by the fact that at times the IAVI partnership exhibits characteristics of a 'bottom-up' partnership. For example, as I have outlined, KEMRI has traditionally collaborated with research organisations from the developed world in order to gain expertise and resources. Similarly KAVI has collaborated with others in the past in a similar way. The decision to collaborate was not thrust upon the research centres although IAVI had wanted to partner with them. The research centres could see the benefits and gains to be made from being involved with IAVI and made a calculated decision to be involved. It was not felt that they had needed IAVI, although they have benefited from them.

For example one member of KAVI told me that "we have interests together clearly of mutual benefit to both the University of Nairobi and IAVI" [KAVI3]. This represents a common sentiment within the research organisations that the partnership with IAVI is beneficial, that it has been useful for them to partner with IAVI but that they could also get this benefit from others should they need it. A number of PIs that I talked to highlighted the existence of other partnerships that the research centres already had and how these would continue to sustain the research groups if AIDS vaccine research through IAVI was not taking place. This is another example of the complexity of the relationship between IAVI and the research organisations. While the partnership exhibits characteristics of a parental partnership there is a degree of agency behind the activities that have taken place. It has not been a completely

passive one-way provision of assistance similar to that which a mother would give a child.

4.3 Visualising the partnership in a wider sense: a fried egg or a walnut whip? [23]

Up until now I have been treating the relationship between IAVI and the research organisations as the main, perhaps the only, collaborations IAVI has with actors in Kenya. While the trial site activities of the research organisations are the main focal point of IAVI's activities in Kenya, the IAVI partnership is larger than this in Kenya. The interactions include those with the wider community around the trial sites managed on a day-to-day basis by the research organisations. They also include IAVI's relations with a number of other stakeholders in the country from healthcare provider groups to government ministries. I shall now outline how IAVI interacts with these different stakeholders in relation to the collaborative arrangements IAVI has with its scientific research organisation partners.

The activities that KEMRI-CGMRC's IAVI project or KAVI conduct on the ground within its trial sites are integral to ensure the success of IAVI's ability to see an effective and affordable AIDS vaccine developed. Although at times there is confusion as to the identity and allegiance of staff within these trial sites, IAVI has little day-to-day interaction with the projects which act as collaborative 'contractors' of IAVI at the country level. The research organisations take care of the day-to-day activities that are conducted around the trial sites. This is the central arena of activity within the IAVI partnership in Kenya and all other activity occurs around it. As such, at country level, a description of IAVI's activities places these activities in the centre.

[23] A 'Walnut Whip' is a chocolate confectionary made since 1910 by what is now Nestle Rowntree. It is perhaps not the best food analogy to use being a brand of chocolate confectionary limited mostly to distribution in the UK by a multi-national company with a dubious history of working in developing countries. However, the confectionary shape fits the requirements well. In essence, it resembles a three-dimensional conical pyramid with an external coating topped with an oval three dimensional disk. (For more details see: www.nestle.co.uk/OurBrands/AboutOurBrands/Confectionery AndCakes/Other+Chocolate+Bars.htm – accessed on 21/11/07)

In describing the relative place of the trial sites within the IAVI partnership one member of IAVI used the analogy of a fried egg (see Figure 4.2). They outlined how IAVI operates at different levels and at each of these it interacts differently and to varying degrees of 'partnership' with its collaborators. The fried egg version of the IAVI collaboration sees the trial sites in the middle, as the yolk, the focal point of the collaboration. The 'white' of the egg is made up of national level policy and advocacy stakeholders varying from those placed close to the 'yolk' of the trial site such as public and private healthcare providers to the government ministries at the outer edge. However, such a uni-dimensional description of the collaboration leaves out where IAVI as an organisation fits within this. This highlights an IAVI perception of how it fits within this partnership placing an emphasis on local ownership within the partnership. This neglects to recognise the complex linkages and information connections outlined in the previous sections of this chapter.

In fact it may be more useful to consider the collaboration through a multi-dimensional visual similar to a walnut whip chocolate confectionary to use another food analogy (see Figure 4.3). IAVI is the walnut on the top connected both to the trial site (represented by the mallow centre of the confectionary) and the surrounding national enabling environment made up of all other actors involved including universities, hospitals, government ministries and community organisations (represented by the chocolate coating). Considering the Kenyan IAVI partnership in this multi-dimensional visual also recognises the opportunities for multiple interactions by all those involved in the partnership.

The systemic nature of the IAVI partnership is exemplified by the fact that IAVI's activities with the exterior entities (the chocolate) – the national healthcare providers, government agencies, international organisations working on the ground in Kenya – has resulted in a countrywide collaborative mechanism being developed. My observations and data from the interviews highlighted the creation of a wider and informal AIDS vaccine research network in the country. This seemed to be being created particularly as a result of efforts by IAVI's regional office and its interactions

with the Government of Kenya and different research groups (not only KAVI and KEMRI-CGMRC). The network occurs as a result of IAVI's support of the AIDS vaccine sub-committee within the Ministry of Health and is evidenced by joint meetings and workshops between AIDS vaccine research organisations to discuss issues and dilemmas facing them (for example in terms of lab diagnostics and the setting up of CABs etc.) As such this provides an introduction towards thinking about the IAVI partnership in a holistic systemic manner as will be discussed in the next section and in Chapter Six.

One of the mechanisms through which this wider AIDS vaccine research network or system is created and maintained is through the existence of what could be called 'knowledge brokers' (c.f. Chataway, Brusoni, et al., 2007; Hargadon and Sutton, 1997; Mosse and Lewis, 2006a). The collaborative activities that take place between those involved in the wider country AIDS vaccine research network creates a variety of linkage points that act as conduits for information between the various members of the IAVI partnership in Kenya. IAVI's New York office is the central and uppermost entity in the IAVI partnership. The entry point to Kenya (or any other country in East Africa) is, particularly for the CRP work but not necessarily for the scientific research activities, through the Regional Office in Nairobi. The research organisations in Kenya interact with the Regional Office and New York and act as the conduit for information from the trial site communities. IAVI's Regional Office in Nairobi acts as the conduit of information from the wider AIDS vaccine research collaborative network in Kenya to the research organisations and IAVI in New York. This notion of actors and organisations acting as knowledge brokers will be discussed briefly in the next section and in more depth in Chapter Five.

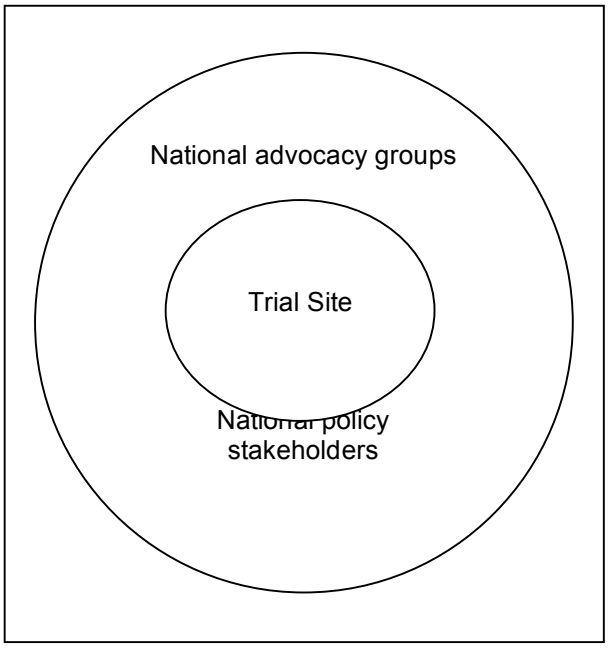


Figure 4.2 IAVI as a fried egg

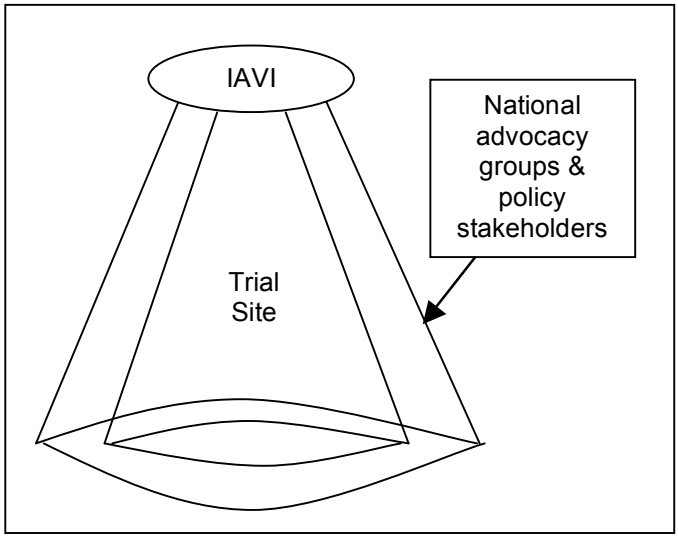


Figure 4.3 IAVI as a 'walnut whip'

4.4 Understanding the partnership

My study of the IAVI partnership at a country level has engaged actively with the question of how partnership takes place and what the implications of this are on those involved in the partnership in terms of their participation and their activities. It has also looked at the different levels at which the partnership takes place and the different actors involved in various aspects of the partnership activities. In so doing, this chapter has highlighted that how the IAVI partnership plays out on the ground in Kenya is both an example of greater empowerment or 'power to' local partners as it is of less participation and 'power over' local partners by others (Nelson and Wright, 1995). The way IAVI, and its research partners in particular, interact is both an example of bottom-up participation and partnership decision making (and thus power relations) as it is top-down. This interplay of two very different participation and decision-making types creates a third form of 'parental' partnership whereby the role of the main partners is played out in a seemingly more traditional sense of donor vs. recipient.

The result is that to understand the way the IAVI partnership operates and is understood on the ground in Kenya it is necessary to embrace the complexity of different types of partnership and a variety of interactions between a large number of different stakeholders each with their own requirements and agendas. The complexity outlined within the IAVI partnership in Kenya emphasises the difficulty of attaining 'true' or real partnership providing justification to calls for the rejection of the partnership term made by some scholars as outlined in Section 4.1. However, part of the complexity is that partnership activities still take place; that it is possible for 'effective' partnership activities to be achieved within the context of unequal power relations reducing the ability to totally reject 'partnership' as a concept. I will now discuss these issues in greater depth.

4.4.1 Complexity

IAVI is a complex interplay of entities. On the ground in Kenya it acts as a collaboration with the appearance of being a traditional development assistance 'them versus us' scenario. In particular, it looks like a parental collaboration. But at the same time, each partner is benefiting from taking part. IAVI is ensuring progress towards the development of an effective vaccine against HIV/AIDS. There are benefits for Kenyan institutions to become engaged and build capacity (as the next chapter will discuss in more depth) in certain areas which would not have been there before. As such it cannot simply be understood in terms of 'he who pays the piper calls the tune'.

This adage in this chapter's title refers to the idea that whoever bares the cost should have authority over a project. This adage was mentioned by a KAVI staff member when describing the relationship between IAVI and KAVI to me. However, as I have shown in the previous sections, such a one sided and power dominated relationship tells only one part of the Kenyan IAVI partnership story. This is because IAVI works in many different ways in Kenya depending on its level of activity. From the activities I witnessed and the comments I received from those who work with(in) IAVI it would appear to act as a collaborator with research groups, government authorities and NGOs through formal and informal contractual mechanisms. Its activities have a number of different levels – described by one member of IAVI like the rings of a fried egg but which may be more like a walnut whip – and at each of these it interacts differently and to varying degrees of 'partnership' with its collaborators. This complex nature of IAVI's collaborative activities and the interplay of different forms of 'partnership' highlight the difficult and contested role power plays in such arrangements.

The IAVI partnership is a multi-level, multi-powered partnership. It works as a PPP globally while on the ground in different countries it works as a collection of different partnerships and loosely formed consortia and collaborations. The partnerships are made up of different actors each with a different power base,

differing expertise and different goals. As the partnership has progressed the skills and expertise of the research organisations have grown and the degree of involvement has changed (for example they no longer have a full time IAVI employee based at KAVI). As the goals have changed so too has the degree of interaction different people had. It becomes difficult to say who is 'them' and who is 'us'.

The IAVI partnership in Kenya is therefore not one dimensional and nor does it take place only around the trial sites as it refers to more than simply the interactions between IAVI and the research organisations. The IAVI partnership in Kenya is made up of a number of different partnerships with different identities and operations depending on the role and type of power relations that dominate. The result is a complex web of different types of collaboration or 'partnerships' between IAVI and various actors in Kenya around AIDS vaccine research. For example, the type of interactions IAVI has with KAVI and KEMRI-CGMRC, as research organisations, is different from that which it has with other organisations within the wider health, research and policy arenas in the country. The former is dominated by contractual relationships which as was highlighted earlier in this chapter is not sufficient for 'true' partnership (Nishter, 2004).

4.4.2 The difficulty of attaining true partnership

The difficulty of attaining 'true partnership' has resulted in much of the international health policy literature on PPPs and partnership discussing the governance issues involved predominately from the standpoint of general policy prescriptions in relation to PDPs rather than in terms of the in-depth institutional realities on the ground in developing countries (c.f. Buse and Walt 2000; Yamey 2002; Buse and Harmer 2004; Wildridge, Childs et al. 2004; Buse and Harmer 2007). For example, Richter (2004) points out that PPPs are not new and that the public and private sectors have been interacting for many years. The difference she states is that there is now an idea that such partnerships are built on a basis of shared decision making with little consideration as to the risks involved and who could lose. Richter therefore calls for an emphasis to be placed on public interest and on impact towards

better health for all by such partnerships. The High-Level Forum on the Health MDGs Working Group on Global Health Partnerships (2005) has called for a number of best practice principles to be used as the basis for such partnerships the first of which is the need for stronger local or country involvement and ownership of activities.

This is not to say that none of the health policy literature considers these issues. Muraskin (Muraskin, 2002; Muraskin, 2004; Muraskin, 2005), for example, has noted the difficulty that early versions of PDPs, particularly the Children's Vaccine Initiative (CVI) and the more recent Global Alliance for Vaccines and Immunisation (GAVI), have had in trying to negotiate between the bottom-up and top-down hierarchies that can be in existence simultaneously. For example, he has highlighted (Muraskin, 2004) the need for GAVI to conduct its activities in a top-down manner to get activities started but in so doing how it created tension between prioritising the funder's objectives and the needs of individual country governments. He relates this to a tension between a systems approach that looks more holistically at how countries set their own priorities and a disease centric approach based on saving lives. This dichotomy between systems or processes and health targets is discussed in more depth in Chapter Six.

Studies such as Muraskin's that take an in-depth look at the way partnership activities take place are important as they bring out the problems with partnership terminology. Widdus' definition of partnership given earlier takes into account that the distribution of risks and benefits will not necessarily be an equal one. However the concept of partnership assumes still that there will be an equal decision making opportunity for all parties to agree to such unequal outcomes – that as Crewe and Harrison (1998) stress, there will be the same ability to 'articulate' within a partnership or as Hirschmann (1970) argues there will be sufficient ability of all partners to have their 'voice' heard. However, this ability to articulate is not static. As partnership takes place, so power and politics within a partnership shifts as activities are undertaken, knowledge and resources are gained and imparted and the outcomes of the collaboration worked towards. Thus articulation of 'voice' becomes

related to power and politics flows in terms of decision making, resource allocation etc.

Within the IAVI partnership it is possible to see that there is certainly a partnership taking place but articulation of 'voice' is related to power and politics flows, particularly in terms of IAVI's collaboration with the research organisations. This is very much based on an unequal division of resources and demands despite some 'local empowerment' with day-to-day decision making in the hands of the research organisations. Thus, the relationship between IAVI and the research organisations can at times still be summed up by the adage 'he who pays the piper calls the tune'.

The complexity of the partnership means the partnership in Kenya takes more than one form at any one time. While partners may benefit from taking part in the IAVI partnership, they do not have equal power relations within this partnership. The relationship between IAVI and the research organisations of KEMRI-CGMRC, and KAVI in particular, is always going to be an unequal relationship when Kenya suffers from a shortage of skilled staff and the facilities from adequate resources to undertake vaccine research. These capacity issues will be more fully discussed in the next chapter of this thesis.

In all three forms of partnership that are exhibited within the relationships between IAVI and the research organisations there is still a resonance of 'them' and 'us'. Despite a degree of local ownership, the IAVI partnership can be seen as the same donor-recipient relationship of old, in new packaging (Crewe and Harrison, 1998). It is interesting to note that a previous President of Kenya, Daniel Arap Moi, apparently used the adage of 'he who pays the piper…' to refer to the relationship between developed and developing nations during his time in power. This is perhaps not surprising given the reality of international development activities in recent years outlined earlier in this chapter. The rise of PPPs can be seen to fit within the rise of the neoliberal agenda and the return towards old style donor-recipient relationships as outlined by the post-development school as will be discussed in Chapter Six.

4.4.3 The chance of effective partnership

However, while 'true' partnership may not be possible, the IAVI partnership in Kenya does appear to have characteristics of an 'effective' one whereby those involved in the collaboration efforts attain goals that they expected. This appears to be particularly the case in relation to the way IAVI and the research organisations of KAVI and KEMRI work together in the sense that they need each other. This complicates the argument that this relationship can be summed up by the adage 'he who pays the piper calls the tune'. While at times this may be the case, it occurs within the context of activities taking place as needed and partners gaining benefits.

Uneven and unclear partnership mechanisms around a PPP do not mean complicated and unbalanced partnership mechanisms cannot assist in vaccine development. As will be outlined in more depth in the next chapter, the IAVI partnership has not only built capacity within the research organisations in Kenya to conduct vaccine research at their trial sites but has also increased the knowledge flow and communication that occurs on the issue of AIDS vaccine research (and HIV/AIDS prevention more generally) in Kenya (and internationally) as well as boosting funding to an area of neglected disease health research. As this chapter highlights, further success and the degree to which different forms of capacity are being built is however dependent on the form in which collaborative mechanisms are developed and evolve over time.

There is mutuality in the need for the partnership between those involved in the IAVI partnership in Kenya, if not joint ownership and equality. While I was doing my fieldwork, I was told on many occasions that IAVI and KAVI/ KEMRI-CGMRC share common interests and that they "cannot go it alone" anymore as they need each other. IAVI requires the trial sites and KAVI and KEMRI-CGMRC need either financial support, technical or skills support. The latter appears to be the case in relation to the IAVI partnership with KEMRI-CGMRC. KEMRI itself is an established research organisation; it has access to funds and has a strong tradition of recruiting, and training, the best research scientists in Kenya. However, it had never conducted AIDS vaccine research before and hence benefited from collaborating with IAVI in terms of gaining technology and skills. While this means KEMRI-

CGMRC, like KAVI, benefits from the partnership with IAVI, the relationship it has with IAVI is different. This is because being more established as an entity IAVI has been more hands-off in its relationship with KEMRI-CGMRC when it comes to the running of the research projects then KAVI has done initially. KEMRI-CGMRC has not gone through the same 'nurturing' process that KAVI has had to.

While the form of the partnership activities may differ, all the parties were involved in either the contractual or coalition collaborations with IAVI because they needed to be involved. There was a feeling that it was impossible to go it alone. Working together creates a better situation whether it is in terms of more vaccine research being undertaken by research organisations or more dialogue around AIDS vaccine research and HIV/AIDS prevention generally in the country through wider AIDS research network activities.

Thus the partnership may not be a 'true' partnership in the sense of each partner being equal in their ability to articulate their 'voice', with the partnership exhibiting examples of both a 'top-down' partnership and a 'parental' partnership, but the partnership has been 'effective' in terms of assisting partners to benefit. One of the reasons for this, which will be discussed in much greater depth in the next chapter, is that the partnership works because of the role different entities play as conduits of information and knowledge. This is especially true in terms of the role IAVI plays in ensuring knowledge and resources are created or accessed and passed on as needed as will be discussed in the next chapter. As such the partnership and the power relations within the partnership are defined by different strategic relations and their negotiation. Thus, it is the negotiation that occurs between actors that is important rather than concepts of partnership per se that by definition reduce the emphasis on conflict, tension and unequal power relations. There is therefore a need to move beyond value-laden notions of partnership which will be discussed in the next section of this chapter.

The role of different entities as conduits of information builds on the notion of IAVI as the 'parental' partner. There has been some research done that suggests IAVI may

undertake a broker or integrator role when it comes to its knowledge dissemination activities (Chataway, Brusoni, et al., 2007). However, the idea that there is a parental form of collaboration taking place suggests that it does more than this, that it has a larger coordinating role at the country level, and particularly in relation to the activities of the research organisations, that it can be likened to that of a parent. In this way IAVI ensures that everything from financial resources for lab equipment to training of CAB members and the discussion of trial results occurs as it needs to. It uses the pool of internal expertise it has in-house to aid its partners on the ground in Kenya build the skills and capabilities to undertake clinical research activities in the area of AIDS vaccine development.

However, it is not simply IAVI that acts as a conduit of information and resources. The creation of a wider AIDS vaccine research network in the country means that there are increased channels of information exchange in existence. For example, KAVI's lab staff were used as conduits of information during training sessions held with other researchers conducting AIDS vaccine research in Kenya but who have not been directly involved with IAVI studies. During these sessions, lab staff translate and 'gate-keep' information (determining when and if to inform others) about how to perform the necessary lab tests for use in AIDS vaccine clinical research.

Related to these knowledge exchange activities is the role they have had on increasing the linkage occurring between innovation and healthcare actors. The Kenyan IAVI partnership is more than simply the relationship between IAVI and the research organisations involving national advocacy and policy actors involved in healthcare issues. As a result, the IAVI partnership is made up of actors from a variety of fields, including those from the healthcare sector, and not simply from the science or research communities. This is another example of the complexity of the partnership. It also highlights the difficulty of understanding where the Kenyan IAVI partnership starts and finishes. This is an example that highlights the holistic nature of systems that was introduced in Section 4.3, will be discussed further in Section 4.5 below and in Chapter Six.

The fact that IAVI is not the only broker of knowledge or resources within the partnership, and the problems of understanding where one partnership starts and another ends, acknowledges the difficulty of determining who has 'the' power and whose power and knowledge counts or is important within the partnership. Mosse and Lewis (2006a) acknowledge that the notion of brokers and intermediary actors is useful in understanding the way actors negotiate their relationships with each other but that they can do more than simply show the "a priori existence of social and institutional realms" (Mosse and Lewis, 2006b: 13) which in the case of the IAVI partnership in Kenya is the dominance of donor vs. recipient relations. Mosse and Lewis stress the existence of multiple brokers who each have a role in creating what becomes the overall system of activity. Borrowing Latour's (2005) concept of 'translation', they argue this is because all actors work to enrol others to create order and maintain interests (the act of translation) which works to create what becomes seen as the overall system. However they also highlight how the "dominant or official narratives of agency and history" (Mosse and Lewis, 2006b: 16) tend to remain dominant as a result of this translation.

Certainly this dual existence of a multiplicity of actors, power and knowledge of different levels of partnership with a continued underlying dominance of 'he who pays the piper calls the tune' can be seen within the IAVI partnership in Kenya. On the one hand there are numerous actors each with their own agendas and requirements involved in both the IAVI partnership and the wider country level AIDS vaccine research network. At the centre of the IAVI partnership are the needs and requirements of IAVI and the research organisations, KAVI and KEMRI-CGMRC. Activities within this partnership, and the functioning of the partnership itself, occur as a result of the nuanced interplay of the different actors, their needs and requirements, together with their negotiation of power, knowledge and interests. This creates the complexity that makes it possible for the IAVI partnership to function and to have characteristics of an 'effective' partnership through the creation of benefits. These activities occur within the context of a continually dominant, unequal power situation between IAVI as 'donor' and the research organisations as 'recipients' and which mirrors post-development analyses of scientific research

partnerships and international development projects. However because there is also the existence of three types of partnerships within the IAVI partnership it is too simplistic to say that the IAVI partnership in Kenya is only an example of a donor-recipient unequal partnership.

The mutual need for the partnership or rather the mechanism of strategic networked relations – IAVI needs the research organisations and backing of the wider health, research and policy consortia while the research organisations and the wider consortia need IAVI, its expertise and funding – together with the continually changing interplay between the power relations within and between the partners within the wider overarching country level AIDS vaccine research network explains why, as Crewe and Harrison (1998) argue, it is not possible to see partnership in the traditional 'them' and 'us' manner. Partnership and development assistance is much more nuanced and complex. There is a greater interplay between the different motivations and incentives for partnering, the various experiences and expertise available and the technologies and mechanisms introduced than is explained in simple 'them' and 'us' terms. As such, this study of the IAVI partnership in Kenya fits with much of the critique (to be discussed in Chapter Six) that has been made of the post-development literature that specifically discusses development activities in terms of this stark binary relationship (Kiely, 1999; Pieterse, 2001).

4.5 Interdisciplinary use of anthropology and innovation systems as a way forward

I have shown how the IAVI partnership in Kenya is not a single entity but an example of complexity that makes it difficult to sum up the relationship in simple binary terms of the 'them' vs. 'us'. However, at the same time, the relationships within the partnership are far from without politics and power and I have shown how it is impossible for true partnership to take place. As a result value laden notions of partnership such as top-down, bottom-up and parental are not perhaps the most useful as individually they are unable to fully explain the complexity that is the IAVI

partnership in Kenya. What is needed is to consider how to move effective partnership activity forward in the context of these uneven power and politics flows. To do this requires gaining more understanding of the partnership process or the institutional arrangements that take place as partnership activity is undertaken.

Considering these from the perspective of anthropology of development, is a useful way forward in this respect. It provides a means to highlight how the collaborative activities 'become real' through the actions of different partners. However, this has also highlighted the importance of not only these collaborative activities but also the knowledge exchange and brokering that takes place as a consequence of this collaborative activity. Stronger acknowledgement of this link, while starting to be made within the anthropology of development literature (c.f. Mosse and Lewis, 2006b) is a central focus of innovation systems thinking which, as already discussed, is being used to promote PDPs such as IAVI within the health research and innovation fields at an international policy level. The innovation systems perspective however is highly instrumentalist and is criticised for ignoring the normative aspects – the power and politics – that are central to understanding the complexity of these partnerships. In order to overcome this and move forward analysis of PDPs such as IAVI requires an interdisciplinary approach that uses both the anthropology of development and innovation systems thinking. This perspective will be used in the remaining chapters of this thesis in discussing how collaboration and capacity building within IAVI takes place. Therefore in this last section of this chapter I will outline the value of this dual approach. I will start with a discussion of the need to move beyond value laden notions of partnership through the use of thinking from within the anthropology of development and innovation systems literature.

4.5.1 Beyond value-laden notions of partnership

This chapter has highlighted the difficulty of considering partnerships such as IAVI simply in terms of their ability to combat market failure due to the positive role of collaboration in creating trust and reciprocity and so reducing the cost of transactions in the market place. They need to be considered in the context within which these partnerships take place and are more complex than much of the social theory that has

been put forward to promote the market failure argument, or the health policy critiques have made explicit. Current thinking within the post-development literature and also the health policy governance literature notions of PPPs stresses the value-laden notion of partnership (the bottom-up, top-down or parental nature) to the extent of ignoring the realities and complexities that occur within partnership.

There is a need, as suggested by Richter (2004), to move beyond value-laden notions of 'partnership'. What is required is more understanding and awareness taken of the interplay between different entities within a partnership process. Taking as a starting point how partnerships work, rather than simply what needs to be done, as this Chapter has done, provides a means of analysing the complexity that exists within partnership activities. In particular the chapter has highlighted the importance of looking in more depth and more critically at the social aspects of partnership; the need to investigate the partnership process or the institutional arrangements that ensure actors achieve their goals and aims from being a member of the partnership.

It is important to look at what makes a partnership 'facilitatory' or assistive to those involved, thus moving beyond value-laden notions of bottom-up, top-down and parental partnership that tend to be binary to consider what makes a partnership effective where all partners benefit within the context of uneven power relations. The starting point from which to see what is needed to create effective, facilitatory partnership is greater understanding of how partnership's institutional mechanisms function. This provides a starting point, as I shall argue in Chapter Six, to move beyond value-laden notions of partnership particularly if one takes a process perspective as the starting point.

4.5.2 The anthropology of development

In this chapter I have worked within the spirit of ethnography based on thinking within the ethnography and anthropology of development literature, as outlined in Chapter Three, to think about how collaboration takes place within the IAVI partnership in Kenya. This has provided a means to look beyond considering the IAVI partnership as simply a means of combating market failure for AIDS vaccine

development and investigate what it actually means to be part of the partnership and how the partnership takes place. Using this perspective has provided an opportunity to go further than many previous studies of health PDPs that have often looked at their activities from an international level perspective. In so doing, I have been able to provide a way of highlighting how the actors within the partnership make the collaborations "become real" (Mosse and Lewis, 2006b: 13), highlighting their power and politics and thus their complexity that makes them more than binary relationships between a dominant and subordinate actor.

The value of this perspective is that it highlights power and politics within partnerships by emphasising the way actors enrol and vie for support and interests (the process of translation discussed earlier). This makes the partnership a function of what occurs in terms of how they "become real" (2006b: 13) for those involved as a result of their interactions with others. The starting point becomes these interactions and their consequences rather than a predefined definition of 'true' partnership or the correct PPP mechanism.

It therefore provides a means to also move beyond binary distinctions of partnerships as top-down, bottom-up, parental, or 'them vs. us' scenarios. It highlights the true complexity of partnership by considering power and politics as central to understanding how collaboration takes place. Such a perspective therefore means it is possible to not only consider PDPs as another form of 'donor vs. recipient' relationship as espoused by much of the post-development literature and critical health policy literature but more fully understand the nuanced relations that take place and make the partnership the complex network of relations that it is. In this way it sets the scene for being able to really understand what makes a partnership effective within the context of uneven power relations and what needs to be done to make it more facilitatory or beneficial to those involved.

4.5.3 Innovation systems

Looking at how a partnership can be facilitatory is an integral part of innovation systems thinking. The IAVI partnership and the actors it includes have

characteristics similar to that of a type of 'innovation system' or a networked group of actors all of whom have a function in facilitating the production and successful delivery of a product. Thinking about the IAVI partnership on the ground in Kenya in this way is useful because of the focus it places on collaboration and knowledge exchange. Innovation systems perspectives, as previously introduced acknowledge and stress the importance of these process type factors as being important for ensuring innovation activities take place and goals are met.

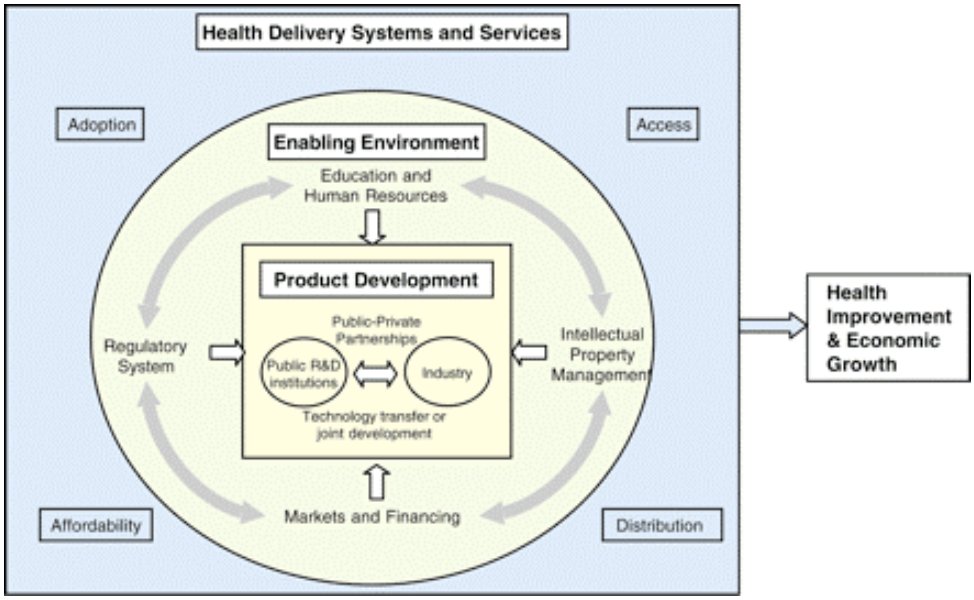
The Kenyan IAVI partnership engages in health innovation activities due to the dominance of a business model which places its biomedical research activities first and foremost with all other activities being seen in terms of their 'supportive' role. The result is that, primarily, the role of PDPs such as IAVI is to innovate – to develop a new or useful product and move it into the market place (Freeman, 1982) – being set up as incentive mechanisms first and foremost for health product development for neglected diseases.

As such, the international focus of the literature around health research is increasingly discussing PDPs in terms of their innovation activities being seen as 'innovative incentive mechanisms' and examples of Health Innovation Networks (Chataway, Chaturvedi, et al., 2007; Morel, Acharya, et al., 2005). Figure 4.4 provides an overview of the constituent parts of a health innovation network based around a PDP such as IAVI. The role of PDPs is focused on the products that they work towards and the best way to incentivise their development; their innovation. Since the first of two meetings supported by the Rockefeller Foundation at their Bellagio Study and Conference Center held in 2001 the international discussion has focused on the role of health innovation (Mahoney, Krattiger, et al., 2007) and more specifically on the importance of promoting health innovation networks or systems as a means of incentivising health product development (c.f. Morel, Acharya, et al., 2005, Mugabe, 2005, Thorsteinsdottir, Quach, et al., 2004). Health innovation ideas are built on a systems perspective that developed within the innovation studies field (c.f. Edquist, 1997; Freeman, 1987; Lundvall, 1995).

There have been calls for the creation of health innovation systems at a national (c.f. Mugabe, 2005) and global level (Mahoney and Morel, 2006). The idea of a 'health innovation system' is used to describe the network of institutions whose "interactions and activities generate and/or use scientific knowledge and produce as well as apply technologies to solve specific disease problems" (Mugabe, 2005: 11). The emphasis is placed less on the institutions involved and more on the requirements or functions necessary to create an enabling environment for successful product development (Chataway, Chaturvedi, et al., 2007; Mahoney and Morel, 2006; Mahoney, Krattiger, et al., 2007).

IAVI can be seen as being a type of micro innovation system or network but also a core part of wider national and global health vaccine research networks or innovation systems; the grouping around which innovation towards AIDS vaccine development takes place and is promoted (Chataway, Chaturvedi, et al., 2007). Such a concept acknowledges the difficulty of bounding systems geographically as health problems and knowledge become increasingly globalised (Lee, Buse, et al., 2002) but also acknowledges the existence of smaller sub-systems that focus on specific issues or problems and go towards making up the larger national and global health innovation systems.

Figure 4.4 An example of a health innovation network



(Taken from Morel, Acharya, et al., 2005)

What is particularly interesting about the innovation perspective in relation to PDPs is the emphasis placed by innovation systems thinking on collaboration and knowledge flows which this chapter has highlighted are important in understanding how partnership institutional arrangements take place and are managed. The emphasis within innovation systems thinking is on collaborative activity that moves knowledge production beyond a linear and top-down model emphasising the complex, overlapping connections between a variety of stakeholders involved both within the main day-to-day activities of product development and within the wider enabling environment or innovation systems.

4.5.4 Problems with innovation systems

Innovation systems thinking is however still a highly instrumentalist view of partnership. One of the biggest criticisms made of innovation systems thinking is that using such concepts does not sufficiently open the "black box" of science and technology by considering the relationships and dynamics of the social processes influencing technological change (Weber, 2002: 327). An emphasis is placed on the "policy consequences" and not the "representational and organisational aspects of the innovation process itself" so that the role of technologies and products is construed in

general overarching terms around 'learning' and 'knowledge' (Jørgensen and Sørensen, 2002: 202). These critiques stem from the emphasis the innovation systems approach places on criticising the neoclassical explanation for technological change (Jørgensen and Sørensen, 2002). Similarly, it may be due to the emphasis it places on economic growth and the related emphasis on macro level explanations[24].

As such it seems important, if systems concepts are to be used effectively, for two things to occur. Firstly, that there are more attempts to delineate the actors involved in innovation, health research and healthcare activities when developing policy recommendations if using systems approaches. It is important to know where the boundaries to a system are; to know who is inside the system and who is external to the system (Tait, 2006). The idea of a health innovation network only specifically labels the actors within the PDP but not those involved in the wider enabling environment while at the wider level of national or international health innovation systems less emphasis is placed on defining specific actors over an emphasis on more generic functions of the systems.

However, understanding who the actors are is necessary if one is also going to be able to, secondly, consider how they interact. The location of the actors within or outside of the system will determine the extent to which they influence the activities of other actors within and outside the system. Tait (2006) argues that those actors within the system are those under the system's control while actors that affect but are not controlled are external actors to the system. In such a definition the boundaries of the health innovation system would be re-drawn to those of the IAVI partnership between IAVI and its contracted partners only with all other actors as external to it.

Such delineation provides a useful way of dividing up the power relations that have been highlighted in this thesis but go only so far. They are still unable to sufficiently communicate for example the complicated two way relationship between IAVI and its regional office and certain Government of Kenya ministries which might be

[24] Innovation systems thinking developed out of a quest for explanations for why some countries developed faster than others. In particular why certain Asian countries in the 1980s experienced rapid macro economic growth.

considered external to the system. Particularly as, based on this analysis, who is internal and who is external to the system is determined by who is in control. As such, Clark (2006) has argued that innovation systems concepts should be seen more as metaphors to highlight the importance of greater linkages and knowledge exchange rather than as prescriptive and testable theories as to how situations should be. When considered in this manner the notion of 'systems' become a useful way of mapping the whole assemblage that makes up the AIDS vaccine research environment and the various linkages between different actors involved.

4.5.5 Taking a dual perspective

The notion of assemblages is discussed in Chapter Six, however at this point it is important to note that the idea of assemblages in this context was developed within the anthropology of development literature. It is here we can see the value of a dual use of this literature with that of innovation systems. Although the innovation systems literature can be criticised for not being sufficiently normative because of its highly instrumentalist stance, it does place a significant influence on the importance of process factors that are necessary to achieve the end point (this becomes increasingly clear in the next two chapters of this thesis). When combined, as this thesis does in the next chapters, with the critical and more normative perspectives from anthropology of development it can provide a way of considering the innovation activities by IAVI in Kenya in a more holistic way. This moves beyond a value laden notion of partnership used by many of those who have previously considered PDPs. It considers the value of PDPs in ways that enhance and yet also go beyond their ability to combat market failure, building on the social theory that is used to promote such partnerships.

Moving beyond value-laden notions of partnership using a dual perspective that links innovation systems ideas with those from within anthropology of development thinking builds on the critiques of the social theory on partnership and social capital outlined in Chapter Two regarding the capturing of these normative views. While starting from a normative position that recognises the embeddedness of activities within social relations these theories become instrumentalist in providing a

justification for the need for PPPs. As this thesis highlights, the instrumentalist view towards product development PPPs is very much in existence in the justification of, and arguments for, the way IAVI should work. The emphasis is placed on the endpoint; attention is placed on doing what is needed to ensure successful product development, rather than focusing on the way social relations take place within the partnership itself.

Considering partnership from a dual perspective of innovation systems and anthropology of development would be to consider IAVI's activities from both an instrumentalist and a normative position. The former is predominately an instrumentalist view of innovation and development but with an overt emphasis on the importance of process. This therefore is complimented by the more critical and normative focus of anthropology which I have used in this chapter to critique the notion of partnership. Such an interdisciplinary perspective, which the remaining chapters of this thesis use, provides a way of considering innovation activities by IAVI in a more holistic way that moves beyond the value laden notion of partnership.

4.6 Conclusion

In this chapter I have critically analysed the notion of partnership in the context of its use to describe IAVI's activities in Kenya with a variety of different stakeholders in order to address the research question I posed around my first thesis theme regarding collaboration and the rise of PDPs. In particular, I have focused on the relationship between IAVI and the research organisations, KAVI and KEMRI-CGMRC, which is the focal point for the IAVI partnership activities in Kenya. In so doing I have highlighted the difficulties of using current definitions of partnership and to a lesser extent notions of participation to describe the type of collaborative activities that take place in the name of the IAVI partnership in Kenya. The Kenyan IAVI partnership is more than a binary relationship of 'them vs. us' as development assistance projects, particularly science based ones, have been perceived. But at the same time it is not without complex power and politics flows making it impossible to describe it

as a true partnership. It is however at times an effective partnership as its activities benefits those involved, although not necessarily equally. It is effective because of the focus that is placed on collaborative activity and in particular due to the consequential impact of knowledge exchange between a variety of stakeholders. This will be discussed in more depth in the next chapter, however, it has specifically highlighted the way linkages are made between a diverse array of stakeholders. This relates to the research question of the second theme of my thesis regarding the linkage between innovation and health. The partnership is more than simply the relationship between IAVI and the research organisations as it involves national advocacy and policy stakeholders as well as being part of a wider country wide AIDS vaccine research network. This is made up of stakeholders from a variety of fields and not simply from the science or research communities.

Chapter Five

Capacity building:

Training and resources or more?

The previous chapter highlighted how innovation systems thinking places an emphasis on collaborative activity and knowledge exchange in order to facilitate health innovation activities. Collaborative activity and knowledge exchange are examples of 'process capacity building'. This form of capacity building, as I outline in Chapter Two, is about building long term holistic processes through strengthening institutional level linkages and the macro level enabling environment. These are examples of other functions of partnership that build on the social theory put forward to promote PDPs such as IAVI. At the same time this creates new forms of value added, or benefits gained, for those involved in the partnership activities than simply reducing the market failure. Thinking in these terms does not ignore the fact that partnership is always unequal and difficult to classify but does mean it can facilitate partners involved to be effective and achieve their own goals in various ways.

This chapter looks in more depth at this concept of process capacity, how it takes place within the IAVI partnership on the ground in Kenya and how it differs from other forms of capacity building activity. In order to do this, I start this chapter by considering the changing attitudes towards capacity building within the international development field, the increasing importance being placed on innovation and, as a result, more attention being focused on learning and collaboration. I then outline the different types of capacity building that can be found to occur within the IAVI partnership in Kenya. These findings lead to a discussion of how IAVI 'does development without doing development' by engaging in capacity building not as an overt activity but as a consequence of working towards its goal of developing an AIDS vaccine using a private pharmaceutical business model of organisation. I

finish the chapter by discussing how, despite this lack of overt attention on process capacity building, IAVI's activities have lead to process capacity taking place and therefore to a linkage of actors and activities from within the often separate fields of innovation and healthcare. I conclude by arguing that analysing IAVI's activities within an ethnographic/anthropological rationale and with insights from innovation systems thinking provides a means of getting to grips with the role of process capacity in a way not previously considered.

5.1 What is capacity building?

The view of capacity building through knowledge exchange and improved networking is at odds with the traditional argument in the development sector that to develop capacity it is necessary to invest in tangible infrastructure and personnel (Nuyens, 2005). This alternative view has its roots in changes in the way development assistance has been viewed. There has been an increasing recognition placed on the importance of innovation for economic growth and prosperity. Related to this last point, the field has also seen the increasing influence of thinking from within innovation studies and related management literatures on the way development and innovation in developing countries takes place. In particular, this is the result of an emphasis each literature places on learning and collaboration. I will now briefly discuss each of these influences before discussing how little impact they have actually had in reality on the way development assistance takes place. This is in part as a result of the rise of neoliberal thinking and an increasing emphasis being placed on quantifiable indicators and outputs at the expense of process monitoring activity.

5.1.1 Changing views in development assistance

A view that equated capacity building to investing in tangible infrastructure and resources was the underlying theme of technical assistance programmes until the 1990s. As outlined in Chapter Two, capacity building was seen as a necessary part

of international development aid activities and in fact was often synonymous with development assistance activities. During this time, very often, conducting any form of collaborative development assistance activity between partners in developed countries and those in less developed countries was seen as a developmental activity; it was equated with both international development assistance and capacity building. Traditionally development assistance took the form of focusing on individual level retooling and training – ensuring infrastructural resources and trained personnel where available. This supply side dominated approach assumed that once equipped, innovation would logically follow (Velho, 2006).

However, as I have outlined in Chapter Two, with increasing recognition of past development failures, the emphasis has shifted, since the 1990s, from focusing on building individual level capacity through training and infrastructural resource support to definitions that acknowledge the importance of taking a holistic and systems approach (Horton, Alexaki, et al., 2003; Milèn, 2001). Thus, in keeping with the acknowledgement that partnership is important, the capacity building literature has been increasingly focused on the importance of interactions, network relations and the multiple forms of knowledge that are important (Milèn, 2001). There is recognition that innovation and knowledge production does not happen in a linear fashion but is the result of multiple interactions between groups of stakeholders within "research-producing communities" and "research-using communities" that make up a complex research "ecosystem" (Csazzar and Lal, 2004). There is recognition that training, including more formal academic training (Velho, 2006), may not be sufficient and that:

> "Whereas the initial transfer of knowledge is often rapid and can be achieved in an intensive training workshop, the implementation process is gradual and requires sustained, long term follow up." (Harris and Tanner, 2000: 818)

Thus there has been increasing emphasis placed by development assistance practitioners and health research analysts on building more process related capacity at the institutional and macro levels. These are the two activities that I collect together under the umbrella term 'process capacity'. Institutional capacity works towards the strengthening of institutions and organisations – the meso level of any

activity – and macro or system level capacity building relates to the creation of supportive enabling environments and the development, in this case, of national health research systems (Nuyens, 2005).

With this, there has been an increasing emphasis put on partnerships as a way to move capacity building forward and partnerships in themselves are seen as a form of research capacity strengthening by increasing knowledge exchange through improved networking opportunities (Morgan, 2003). Partnerships are seen to bring to health research the opportunity of:

> "increased access to new ideas and best practices, technical expertise, and resources; wider coverage and impact of research benefit; and an increased probability of sustainability recognition and leverage of the research partnerships." (Lansang and Dennis, 2004: 766)

5.1.2 Increasing recognition of innovation for economic growth and prosperity

The emphasis placed on process forms of capacity is also related to the rise of the concept of health innovation, which I outlined in Chapter Two as the generation of new knowledge and products to tackle health problems. In particular, with the rise of this concept there has been an increasing recognition placed on the importance of health innovation activities, and science and technology more generally, for enhancing economic growth and prosperity of developing countries. As I outlined in the last chapter, particularly from the 1970s, with development of the innovation studies field, there has been an increasing interest in understanding why some countries' economies have grown faster than others and the role of innovation activities in explaining these changes using R&D, patents and publications data as proxy measures for such activity.

Within these perspectives the overarching reasons put forward for the promotion of local science and technology capacity building is its potential to create economic growth and improving a country's industrial competitiveness. Yet this ignores the fact that strengthening science and technology capacity can also lead to reduction of disease burden and improvements in health (Freeman and Miller, 2000). This latter

reason is important because developing science and technology research capacity, particularly in the area of health innovation, allows countries to build a cadre of professionals who can interact with international counterparts and focus on developing effective solutions for their current and potential future health challenges (Csazzar and Lal, 2004).[25]

Thus the 1990 Commission on Health Research for Development talked of research in the following manner:

> "Research uses the scientific method to discover facts and their interrelationships and then to apply this new knowledge in practical settings. This process was the means by which the jet engine was invented, the atom split, and the green revolution of the past 25 years generated. Research holds the same promise for health, a promise that we have seen fulfilled with the development of new tools such as antibiotics for the treatment of disease, vaccines for its prevention, and insecticides for controlling the vectors that transmit it. Yet for the world's most vulnerable people, the benefits of research offer a potential for change that has gone largely untapped." (Neufeld and Johnson, 2001: 11; emphasis added)

5.1.3 Increasing attention on learning and collaboration

In explaining how different approaches to innovation activities created the differing growth rates, literature within innovation studies has focused on the role of knowledge exchange and collaboration. In particular, this field of literature stressed the importance of collaboration for successful innovation activities, starting from the same economic reasoning given to justify the need for global health PDPs outlined in Chapter Two that it becomes efficient to integrate and institutionalise (North, 1990). However, it goes beyond this literature in two ways. Firstly, in stressing the importance of the type of connections that take place and, secondly, it emphasises the way knowledge is exchanged through these connections in order to create 'absorptive capacity' or an understanding of the value and use of knowledge.

[25] Obviously – and as outlined by some of the empirical data in this chapter – building a cadre of professionals does not guarantee their retention as highlighted by the increasing literature on the issues and consequences of 'brain drain' (c.f. Honoré, 2002; Lowell and Findley, 2001; Martineau, Decker, et al., 2004; Rapoport, 2002)

This literature places an importance on "interorganisational structure" (Blume, 1992: 37) in innovation and "the role of organisations as operators translating individual subjective knowledge" (Metcalfe, 1994: 933). Particularly, there has been increasing recognition given to the importance of partnerships in producing successful innovation because of their ability to reduce transaction costs but more importantly to manage knowledge:

> "Collaborative ventures are partly defensive innovations in that they are aimed at reducing or sharing risks and costs. They are also offensive innovations in that they extend the skill base of the firm and the range of knowledge available to it and thereby improve its ability to compete." (Gibbons et al, 1994:121 see Hewitt, 2000: 54)

Collaboration in the form of social capital or the networks and linkages that a systemic process create are seen by some as the backbone on which knowledge or intellectual capital and the resulting production capital are created (Lundvall, Muchie, et al., 2003) providing the basis on which absorptive or knowledge based capacity of the system is produced (Narula, 2003). This knowledge capacity and its creation, diffusion and use (the absorptive capacity) is central to innovation. Put succinctly these two premises mean that

> "economic creativity is actually about the quality of "technological linkages" and "knowledge flows" amongst and between economic agents. Where the interactions are dynamic and progressive great innovative strides are often made. Conversely where systemic components are compartmentalised and isolated from each other, the result is often that relevant bodies are not at all productive." (Clark, 2000: 12)

5.1.4 Returning focus on indicators and outputs over process

Despite these changes outlined above and those provided in Chapter Two regarding the rise of process monitoring approaches and the rising importance placed on knowledge management, there is an argument that international development assistance is actually increasingly focused on quantifiable indicators and outputs rather than on process (Cornwall, 2007; Pickard, 2007). This is exemplified by the findings of my case study of IAVI's activities in Kenya, as I shall discuss shortly, but can also be seen more generally regarding the way health product development for neglected diseases is currently promoted. Processes and process capacity are often ignored despite their acknowledged importance within the economic literature used

to promote PDPs such as IAVI and the more critical alternative approaches from the fields of innovation and international development that stress collaboration, learning and process monitoring introduced in Chapter Two. I shall now briefly discuss each of these issues to explain the lack of impact process based concepts have despite being promoted in certain arenas.

Mosse, Farringdon and Rew published a book entitled *Development as Process: Concepts and methods for working with complexity* (1998) which had as its central focus the role of process monitoring mechanisms as a way to understand "the actions and events arising from planned inputs and the means by which outputs are produced" (1998: 4). This book epitomises an emphasis placed in the 1990s by some actors within the development field on considering how activities take place in order to understand better how to more effectively reach goals and outputs. Cornwall (2007) however argues that such arguments are no longer fashionable within mainstream development policy and practice as an emphasis is being placed on 'results-based management' and the notion of 'best practice' is promoted as part of an attempt to homogenise policy prescriptions and results. She writes:

> "The days when process showed a glimmer of becoming fashionable came and went very quickly; today's development is all about the quantifiable and measurable." (Cornwall, 2007: 477, original emphasis)

Pickard (2007) in the same volume of *Development in Practice* expands further on this. To discuss the nature of partnership within Mexican NGOs he provides a background to the wider policy environment within which these NGOs operate. He argues that the 1990s saw a rise in conservative thinking as the neoliberal economic policies introduced in the 1980s took hold. The result was a change, as I have outlined in Chapter Four, in who sets the priorities in international development projects and partnerships. Alongside this came a change in the definition of 'success'. As I shall discuss further in Chapter Six, success has come to be defined, in terms of "short-term quantification" rather than "long-term processes of social transformation" (Pickard, 2007: 580). This fits into a wider move, as discussed in Chapter Six, within international development towards quantification of projects and programmes against targets such as the MDGs.

The emphasis on short-term gains over longer-term development is very much evident in the following section of this chapter when describing the capacity building activities of the IAVI partnership in Kenya. As I introduced briefly in Section 4.5 of Chapter Four, and will discuss more fully in the next Chapter, the emphasis on different capacity building activities are the result of what can be stylised as two competing tensions at opposite ends of an organisational model continuum. At one end is an emphasis on capacity building and longer term development of local scientific research and healthcare capabilities while at the other is the dominance of a private sector business ethos and a need within international health policy to find a vaccine against HIV/AIDS as quickly as possible.

Both IAVI and health product development for neglected diseases more generally are often dominated by a business ethos emphasising speed and efficiency. As outlined in Chapter Two a focus within international health policy is unsurprisingly increasingly placed on getting a product out to solve a health crisis such as neglected disease development because the disease burden is high. The degree to which this is a focus could be contested by virtue of the use of the term 'neglected' to refer to these diseases. However, the creation of a variety of new PDPs, the new Global Network for Neglected Tropical Disease Control formed in 2006 (see http://gnntdc.sabin.org/)[26] as well as increased policy forums such as both WHO's Commission and the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property as discussed in Chapter Two, suggest attitudes, policy and most importantly the politics of international health policy are changing to reflect increased attention on neglected diseases. These policy prescriptions put forward in connection with these new mechanisms are heavily focused (accept in terms of that advocated by the Global Network for Neglected Tropical Disease Control) on what might be termed 'techno-fixes'. Neglected disease control has been predominately based on the development of medicines and new technological improvements (Hotez, Molyneux, et al., 2007; Labonte and Spiegel, 2003; Unger, De Paepe, et al., 2006). There is a low use or scaling up of existing and often less high-

[26] Last accessed on 10/12/07

tech interventions (Wagstaff, Claeson, et al., 2006) but where this does take place, policy is often not focused on their integrated introduction or on the development of sustainable, long-term delivery mechanisms, hampering their progress (Molyneux, Hotez, et al., 2005)

This emphasis on quantifiable results and definable physical outputs is at odds however with the economic literature which is used to promote the mechanisms by which these results are to be achieved, namely partnerships and PDPs. This literature stresses the importance of good process: the need for frequent interaction; the creation of strong or weak ties; and the building of trust and social capital. It is also at odds with the more critical alternative approaches from the fields of innovation systems that are being put forward to promote PDPs as health innovation networks. Innovation studies approaches stress the importance, as outlined in the last chapter, of strong collaboration and learning as a result of knowledge exchange between different actors involved in an innovation process. Understanding the reasoning for this disjuncture between process and outputs in the policy arena is another research project in itself. It is however important to highlight this disjuncture to give a contextual backdrop to the discussion of my findings that I will now outline in Sections 5.2 below.

5.2 Capacity building within the Kenyan IAVI partnership

IAVI increasingly promotes itself as an organisation that actively seeks to strengthen participation of local researchers and build up local research infrastructure so that an increasing level of decentralisation of activity can occur leading to the creation of long-term sustainable or self-sufficient research facilities (c.f. Hecht, Becker, et al., 2006). In this section I will show that IAVI does build local research infrastructure and that, through the work of the IAVI partnership in Kenya, there is the creation of certain forms of 'process capacity' which are important for ensuring long-term self-sufficient research facilities are developed. The IAVI partnership in Kenya therefore fulfils both traditional capacity building activities at an individual level and goes

some way towards building less tangible process capacity by emphasising macro level capacity building of a wider enabling environment. However, neither IAVI nor the wider IAVI partnership places an overt focus on the institutional or meso level and the importance of building knowledge, information and learning connections between those working in the partnership. The capacity building activities that take place within the IAVI partnership in Kenya will now be discussed in more depth.

5.2.1 IAVI & Capacity Building I – training and resources

When I discussed capacity building with those I interviewed the initial response of those I spoke to was to consider capacity building in terms of training courses and workshops. Most often the first response was to mention a training activity related to Good Clinical Practice (GCP). These training courses and workshops are an easily transferable form of knowledge exchange but which requires interpretation for the knowledge to be taken up in full. When I discussed capacity building activities in more depth I found a distinction was made between the provision of assistance to attend short courses and longer term professional development and academic training opportunities. However, overall, both sets of training where seen as useful and that forms of training were important for all staff not just those involved in the research organisations. Along with training activities, capacity building was also equated to provision of physical resources and equipment. I shall now discuss each of these findings in more depth.

I asked nearly everyone both within and outside the IAVI partnership in Kenya that I interviewed how they defined capacity building. The words that kept coming up were ‘training’, ‘workshops’, ‘infrastructure’, ‘resources’ and ‘personnel’. The training and workshops described (such as those outlined in Figure 5.1) were examples of activities that allowed for the dispersal and uptake of codified or written and easily transferable knowledge forms often similar to those used in classroom teaching. Experts provided information on everything from how to store files as part of GCP to the identification of skin infections or provided ‘vaccine literacy’ (information about HIV/AIDS and the vaccine trial process) to the local community and other relevant stakeholder groups. Clinical research organisations and IAVI staff

at the regional office were also aided in their activities by the provision of equipment, buildings and personnel. The provision of these materials was seen as a form of capacity building, enabling activities to be undertaken that had not been possible before.

GCP training was mentioned first and foremost when discussing capacity building by most of those working at the clinical trial sites and at IAVI. GCP training was seen as the 'minimum requirement' needed by everyone from principal investigators to drivers working on a clinical trial. GCP is an international set of ethical and scientific quality standards developed to guide the design, conduct and reporting of human clinical trials. The importance placed on GCP was summed up for me by one nurse counsellor's comments:

> "Because when we started for example, the first protocol we did I would say we were green. We were not really sure about what we were doing but we did some training. Going for GCP training, that helped us to understand why we are doing what we are doing, which was quite different from when you did it, we did it but we didn't know why we did it, so… we didn't understand the whole situation because even if I did something wrong, I wouldn't even know it's wrong, but with information, like when we had this training, it helped us to know why we do what we do." [Kilifi11]

This idea that GCP can help understanding is a valid although limited statement of what is necessary for real learning to take place based on the findings within the knowledge management literature (c.f. Nonaka and Takeuchi, 1995). As I will discuss later in this chapter, at some point rule following is not sufficient to ensure real learning and knowledge exchange. To be most useful GCP type standardised training requires opportunities for its interpretation. What is required are opportunities to discuss, explore, experiment and learn around aspects of standardised, written down or codified knowledge such as GCP procedures. GCP and other forms of protocol in the clinical setting are used as opportunities for standardising and guiding processes, providing opportunities for coordination and the creation of order out of 'messiness' (Berg, 1998). However, within the order, instability is created, as negotiation is required to ensure tools such as GCP procedures and protocols are taken up (Berg, 1998). As such one of the themes of this chapter is that structured learning and codified knowledge sources are used to

stabilise activities but that actually a more complex relationship takes place whereby interpretation within local contexts is required. This issue will be addressed in a number of places throughout this chapter.

Good Clinical Practice	Training on an international set of ethical and scientific quality standards that guide the design, conduct and reporting of human clinical trials. Undertaken by all staff involved in clinical trials
Good Clinical Laboratory Practice	As above in respect of laboratory practices. Undertaken by all laboratory based staff.
HIV Voluntary Counselling and Testing Training	Training of research centre nurse counsellors in VCT
Communication skills training	Training of staff involved in HIV vaccine trials in report writing, listening, feedback and dialogue skills
Antiretroviral Treatment training	Training of nurse counsellors in ARV science and management
Dermatology Short course	Skin infection management overview for trial site doctors
Community Advisory Board Training	The roles and responsibilities of CABs as well as the basic science, ethics etc. of clinical trials and HIV/AIDS
Peer Leaders Training	Training of Peer Leaders in their roles and responsibilities as well as the basic science, ethics etc. of clinical trials and HIV/AIDS
HIV Diagnostic Testing and Counselling	Training for healthcare providers on how to diagnose test and counsel for HIV/AIDS
Gender Training	Training of healthcare providers on the sensitivities of dealing with HIV/AIDS in women

Figure 5.1 Examples of short training courses sponsored by IAVI

GCP training is an example of the work related training that was the most often mentioned form of training or professional development opportunity provided to members of the IAVI partnership. In fact there was a tension particularly voiced by those working within the trial sites regarding the increasing emphasis IAVI was putting on trial specific training, such as GCP and other short courses, at the expense of more generic professional education opportunities. When IAVI first started

supporting Kenyan research institutions a number of members of staff at the research centres were sponsored by IAVI to undertake formal academic training i.e. Certificates, Masters degrees and PhDs. IAVI has now reduced the emphasis placed on professional development reducing the numbers of opportunities for funded PhD and Masters Degrees. There were conflicting reports among staff at the two research centres as to whether IAVI had just scaled down its support of longer-term academic study or had stopped supporting it altogether. On analysis of the answers given during interviews and other data I gained it would seem that in the beginning – when IAVI only worked with KAVI – IAVI had supported around six staff each year to pursue academic training (Higher Diploma, Bachelors, Masters or PhD degrees). Since 2003/ 2004 this had reduced to around two candidates per site, although around half a dozen people I spoke to were adamant that such support had been halted completely or told me that their request for such support had been turned down. Interestingly while five staff members of KAVI that I spoke to had received funding from IAVI to pursue academic studies (compared to three who were pursuing their studies through their own financial means) only one staff member I spoke too at KEMRI was being funded. This may well be explained by the changing of IAVI policy around 2003/4 towards support of academic study – just as the KEMRI IAVI project was being set up.

The overall impression amongst KAVI and KEMRI-CGMRC IAVI project staff was that a reduction in emphasis on long term professional development opportunities over short courses was not good for the long term development of a cadre of professional clinical trial researchers and the sustainability of the research centres. It was felt that such assistance was required because it is difficult to find courses in Kenya and even more difficult for staff to pay for courses using their own funds, particularly, due to the high cost, should they need to travel outside Kenya to study these qualifications. IAVI staff members, when I discussed this with them, were aware of this issue but stressed that they had their own immediate requirements – the development of an effective vaccine – which had to come first. Such is an example of the tension within IAVI's staff and operations between an emphasis on speed and efficiency of IAVI's pharmaceutical business model and the requirements of its

international development sector origins that will be explained in greater depth in the next chapter.

Short course and longer term academic training were both deemed important to staff at the research organisations because they were both seen as providing a means to understand clinical research processes and concepts. Any form of training was seen as useful. For many people, working at KAVI or on the IAVI-KEMRI CGMRC project was their first introduction to clinical trial research. In KAVI the principal investigators had been involved in clinical research activities before but had not worked on vaccine trials until the partnership with the University of Oxford and IAVI in the 1990s. Only one other member of staff at KAVI, a doctor, had been involved in clinical research before. The novelty of clinical research is less for many working on the IAVI KEMRI-CGMRC project due to the long history KEMRI has of research activities although KEMRI-CGMRC had never been involved with HIV/AIDS research in the past. For over two-thirds of the 62 people that I talked to, especially those within KAVI, training opportunities, and particularly academic training opportunities, provided a means of empowerment and professional development being a way to ensure a long term future in the area of clinical research. Short course training was associated with providing the ability to do more; enabling people to achieve their current tasks much more effectively but also providing them with the background needed to conduct future studies, perhaps not just in the area of HIV/AIDS vaccine research. These attitudes are evidence of the creation of a research culture which will be discussed in more depth later in this chapter but an example of this attitude towards the role of training as a capacity building opportunity is exemplified by this quote:

> "I think IAVI has done a lot for us when you talk of capacity building. Both professionally and for long courses and short courses, we have gained a lot… I've been able to go through my Bachelors of Science in Nursing, which was a distance learning based one. And short courses like VCT counselling and even attending conferences, yeh, to learn about HIV/AIDS. Like, I've attended so many… Yes, we've been quite exposed actually and I appreciate that. It's actually empowered me a lot and it has taught me to be so much more independent. Plus it has broadened my knowledge of the vaccine trials." [KAVI6]

Training was not just associated with GCP nor deemed only important by those working as doctors, nurses and lab technicians at the trial sites. Training was also deemed important for others involved including those working as community mobilisers, peer leaders and on the community advisory boards. For example as one CAB member told me:

> "Part of our work plan for this year, was capacity building in-built in half-hour sessions during our monthly meetings, and that has happened…. My attendance at the workshop in Uganda was part of capacity building… I came back with a report which I shared with the rest… our meetings really are opportunities for that capacity building, because if you share experiences and our challenges you are giving knowledge to one another, in passing information and knowledge." [KAVI20]

Related to this was an emphasis placed on training sessions and workshops as providing places for those involved in clinical research from different sites to come together and share experiences. For example, the nurse counsellors at KAVI and the IAVI KEMRI-CGMRC project held joint supervision sessions in the KAVI and KEMRI projects. These sessions provided a routine setting for feedback, sharing of experiences, training and tip giving that was seen as invaluable. These routine supervision and training exercises provide an example of a less traditional capacity building activity that goes beyond simply providing an opportunity for the dispersal and uptake of codified knowledge. This is therefore an example of both traditional individual capacity building as well as an example of what I term 'process capacity building' which will be discussed in more depth later in the chapter.

As mentioned earlier, capacity building was not simply described in terms of training or 'skilling' of personnel but also in the provision of new personnel, equipment and other resources. IAVI's financial support was very influential in bringing the physical formation of KAVI and the IAVI KEMRI-CGMRC project into being. The basic buildings and staff were already in place at the University of Nairobi to create KAVI. However, for KAVI to become what it is today has taken the purchasing of specific equipment, the building of new labs and the employment of more staff, all of which have been sponsored by IAVI. In the case of KEMRI's IAVI project, although some of the initial physical space existed, as did the personnel, it took

financial support from IAVI to build the CCRC centre, to purchase more lab equipment and fund the employment of project staff.

Provision of such physical support was seen as an important aspect of capacity building activities that IAVI had contributed to each of the research centres. When capacity building was defined, training was often seen as only one part of the process, and was usually followed up by the need for infrastructure or equipment. There was a feeling that training only went some of the way and needed to be supported by physical materials:

> "Capacity building, how I think about it is the enabling of a group of people to do a set of tasks that they wouldn't have done otherwise. So, okay, enabling them to do a task and do it well after some training. Because the capacity building involves personnel, it involves infrastructure and what else? Money, because you cannot do capacity building without these components." [KAVI1]

IAVI has not only contributed infrastructural resources to the research centres. IAVI has also provided physical support to the associated healthcare facilities as well. IAVI's financial assistance for the building of the CCRC in Kilifi is a case in point. The provision of the building adds value to the hospital providing it with a new hospital resource and asset.

Furthermore IAVI has built capacity through building up networks to provide ARV provision to those involved in the trials and the surrounding community. This is also an example of both a traditional tangible resource provision form of capacity building and a macro level form of enabling process capacity building. IAVI has not physically provided the ARV treatment therapies as they did lab equipment for the research centres but have worked to sensitise and stimulate discussion on the issue of care provision to build a referral pathway and supply chain. This has created an enabling environment for more integrated clinical trial research to take place.

5.2.2 IAVI & Capacity Building II – process capacity

Building a referral pathway and ARV supply chain is an example, as I have just illustrated, of macro capacity building opportunities. Capacity building is therefore more than simply building tangible and physical capacity building provided by

resources and training. As this section will outline, the IAVI partnership works towards the promotion of forms of process related capacity but particularly in relation to institutional or meso level capacity, does so, as a consequence of other activities and not as a specific capacity building goal.

In particular I will discuss how in the area of meso level institutional capacity building there is an acknowledgement of on-the-job learning. I became increasingly aware of the importance through work activities of the sharing of lessons and ideas – of knowledge exchange – to ensure codified knowledge was taken up. There is an emphasis placed on codified knowledge through forms as conduits of knowledge exchange with the lab as a central node and stabilising force for such knowledge. However, process knowledge and information exchange are important to ensure forms act as conduits. These activities extend beyond the research site. In particular, I became aware of the importance of not only knowledge exchange but also the importance of learning opportunities.

In the area of macro level capacity building I will discuss how IAVI builds this in two locations. Firstly, within the research sites and the wider research community. A consequence of other capacity building activities, particularly meso level institutional capacity building, has been to intensify the creation of a national research culture around clinical research. This is because IAVI has built systems and infrastructural support, not just within the research site but also within the area of related healthcare provision too. Secondly, IAVI has built macro level capacity within a widely defined policy arena. This includes communities surrounding the trial sites, the healthcare community more generally in Kenya and the more traditionally defined policy arena around the Government of Kenya, regionally and internationally.

5.2.2a Meso level organisational capacity

When I discussed definitions of capacity building with those involved in the IAVI partnership, there were a few people who mentioned the importance of teamwork and the ability to discuss and share knowledge as being important aspects of capacity

building. However, when I asked about the types of capacity building opportunity that were available few people mentioned these types of institutional capacity explicitly. There was some acknowledgement of scientific collaboration and of learning-by-doing but not as an explicit or overt capacity building goal of the partnership activities. However, as my discussions and observations took place – as I shall describe in more depth below – these were very much in evidence.

Through the interviews, discussions and observation of the IAVI partnership activities in Kenya I built up a picture of the types of process capacity building that took place. As I mentioned above, there was an acknowledgement of the importance of 'on-the-job' training, of learning-by-doing. Related to this was the importance of sharing of lessons and knowledge. An example of this is the importance placed on the counsellor supervisions I mentioned earlier. Thus there was an emphasis placed on institutional capacity or the building up of organisational, managerial and day-to-day processes that enable activities to take place successfully. Below I outline the importance of these. In particular, I draw on the discussions I had with one of the trial doctors who discussed these issues with me at some length. She acknowledges the importance of capacity building opportunities that are provided on the job and which are not "directly measurable" and "the kinds of things that you can't really say, 'this is how it helped me'" such as management skills, learning how to relate to volunteers and writing protocols. She told me it is about learning how to think using a "research mind" in a way that makes her "more than just a doctor only".

My observations and discussions strengthened the feeling I came to have of the importance of sharing ideas, lessons and knowledge through the interaction between staff members and with those outside the research setting. As my fieldwork progressed it became increasingly clear that there was a significant amount of process knowledge, information and learning (day-to-day discussion, experience, and verbal validation) that enabled the codified knowledge, information and learning (such as standard operating procedures (SOPs), reports, case report forms, routine meetings, phone calls and emails) which were overtly in evidence and heavily stressed to be transferred, understood and acted upon.

These interactions occurred within the lab as has been discussed by science studies scholars elsewhere (c.f. Knorr-Certina and Cicourel, 1981). For example, I spent some time observing the work of the technicians in the serology and molecular lab at KAVI. I spent my time standing or sitting watching what the lab technicians did occasionally asking for clarification of a procedure or activity they were conducting. Although for the most part the technicians worked in silence and in isolation from one another (each at benches on different sides of the room as per their division of responsibilities) when batches of samples arrived and when samples needed filing they came together to discuss how to proceed against the protocol. There was also an incident which I observed where an alarm sounded due to a freezer door not being shut properly. In order for the incident report to be written discussion took place between three lab technicians to determine the cause of the alarm and the subsequent recording of the event. While these are all probably normal activities of the lab and appear obvious requirements of their work – I certainly naturally assumed discussion would take place at these points – an overt emphasis is rarely placed on the importance such interactions have on the ability for successful implementation of protocols to take place.

During my observations I did not directly see any major discussion regarding the interpretation of test results. However during my discussions with the lab technicians when they drew their knowledge flow maps all the technicians told me of the importance of discussion for lab sample interpretation when there were discrepancies. For example one technician when asked about the information exchange that occurred told me:

> "Most of it is written down and we also have verbal support to go with it. For instance, we may talk of the level of say, haemoglobin about a patient that has already been recorded that is clinically significant or is not significant. We might not have that written down… it's our opinion… but we discuss a lot about the situation we are operating in: the way the machines work, whether they are optimal or whether they have problems." [KAVI8]

Informal discussions also occurred during day-to-day exchanges outside the lab as also acknowledged within the STS discipline (Sismondo, 2004). Discussions took

place between lab technicians and nurses and were as much about interpretation of test results but also the implications for the protocol should timings not be adhered to. For example, one afternoon I was sitting in the KAVI reception at Kenyatta National Hospital when one of the nurse counsellors stopped a lab technician who was passing to ask about a trial participant's test results (belonging to a client that I had seen just go into the consulting room). A heated discussion took place about the delay with the test results and the implications this was having on the nurse's ability to do her job.

While visiting KEMRI-CGMRC IAVI project sites another lab sample was also the cause for much talk. This time the discussion occurred between most staff involved in the project. It started out as a discussion on the interpretation of data results but became a discussion of human error. On the first day in Kilifi I gained a sense of a problem during a discussion with the senior lab technician. He told me he was only able to meet with me at that time because his meeting with the PI of the project had been cancelled. The PI, I was told, was busy dealing with a patient who had been given the wrong test results due to a mislabelling of a blood sample. Over the next few days I came to hear the full story. I was told that after initial testing of blood work, the values showed that one volunteer had become HIV positive. The volunteer was then told, only to hear a few days later – after further examination and investigation – that it was someone else who was in fact HIV positive. While this example can be used as evidence supporting the importance of adhering to protocols, it also highlights the factor of human error which has the potential to collapse a protocol very quickly. Discussion and negotiation were needed to move ahead in the face of the crisis within the KEMRI-CGMRC IAVI project. However, it is also possible to argue that discussion and negotiation – the exchange of information and learning – is needed in advance of the protocol and during its implementation to ensure that it is successfully conducted without such mistakes.

As I have mentioned earlier there is a large literature that acknowledges the importance of this process in the area of innovation studies which builds on work from within the knowledge management field (c.f. Eden and Spender, 1998; Nonaka

and Takeuchi, 1995; Principe and Tell, 2001; Tidd, 2000; von Krogh, Ichijo, et al., 2000). Most influential has been Nonaka and Takeuchi's 1995 book *The Knowledge-Creating Company*. In this book they outline the process by which tacit knowledge becomes 'explicit' (codified and more easily transferable) and the importance of ensuring opportunities for discussion, knowledge sharing and dialogue to assist the take up of explicit forms of knowledge. Nonaka and others (c.f. Quintas, 2002; Tidd, 2000; von Krogh, Ichijo, et al., 2000) have highlighted how in order for explicit knowledge to be extracted and understood movement is required from individual level learning activity to group activity and draw on the work of Wenger (1998) relating to 'Communities of Practice' (CoP).

CoPs are informal social networks of individuals who work together towards shared goals and with shared belief systems. Shared experience within CoPs results in learning. Groupings similar to CoPs, I would argue, appear to exist within the clinical trial sites which engage in IAVI clinical research made up of the doctors, nurses, lab and data technicians whose shared experience ensure knowledge is exchanged regarding the samples and data relating to a specific protocol. They are however different from CoPs in that the emphasis on explicit data forms – on protocols, SOPs and GCP – creates a division of goals, beliefs and values within the clinical research 'team'. The overt emphasis placed within these documents on strict divides between what is deemed research activities and health care provision activities creates difficulties for establishing shared beliefs and goals. I return to this divide later in this chapter in Section 5.4. However, their ability to become CoPs is, I would argue, more directly hindered due to the emphasis placed on codified forms of knowledge and standardised learning mechanisms.

The importance placed on GCP, and particularly the training in these procedures by IAVI and research staff exemplifies the overt emphasis placed on codified or more specifically written forms of knowledge and information (forms etc.) and their use as conduits for knowledge exchange. There are strict procedures in place for the conduct of clinical trials, starting with the training of all staff in GCP. Each trial has a protocol written by IAVI outlining all the specifications of, and procedures to be

undertaken in, the study. This outlines how volunteers are to be recruited, enrolled and monitored during the study, which lab tests and their procedures are to be undertaken, what data is to be collected and stored and their relevant methods, the medical care available to a volunteer and the reporting structure for the study or trial. SOPs are drawn up for all necessary procedures and activities that are outlined in a protocol. As one doctor told me, "We have SOPs for all the different cadres. So everyone knows what they are supposed to do." [KAVI7]

Each time a volunteer visits the clinic a case report form (CRF) is completed and a requisition form for any tests filled out by the doctor to accompany any samples to the lab. The work required to complete the tests on the requisition form is outlined in analytical plans created by the research organisations and approved by IAVI.

Thus, the research process in the clinic and the relationships between the clinic staff are mediated by forms; examples of codified knowledge and information. The way forms are filled in, the activities staff undertake and the interaction they have are based on written procedure and instruction. Outside of everyday friendships and pleasantries, discussion between staff (for example, between the lab staff and the data management staff or clinic doctors and nurses) occurs around the content of forms as rules and procedures are followed in line with the information held within the forms. The forms become 'standardised forms' (Star and Griesemer, 1989), 'immutable mobiles' or 'mediators' (Latour, 2005) around which connections are made and ideas and 'facts' transferred. The information that is transferred is the physical written information on the form, for example, the test results are entered into the CRF and then into the data management system (LIMS) for aggregation with previous results which are used to develop the overall study data reports outlining the results. The idea that these forms are in fact mediating objects – the standardised forms that Star and Griesemer term 'boundary objects' – reinforces that fact that in order for these forms to have value (to be useful) requires an acknowledgement of the social interaction that is part and parcel of learning (c.f. Nonaka and Takeuchi, 1995) in order for these forms to be used successfully as stabilising mechanisms (c.f. Berg, 1998).

On the surface such strong defined procedural processes suggest as one of the data management personnel told me, “if qualified and well trained, its just a matter of getting and following the instructions” [KAVI11].

However, and perhaps obviously, this does not, nor can it, occur silently. As already outlined, it is necessary for discussion to take place about the processes or activities undertaken and the data gained. For example, samples, equipment, data and volunteers do not always act as the protocols suggest they should, often resulting in unintended outcomes (Harper, 2005). I was frequently told of situations where, particularly with relation to one study that was conducted, queries were received from the data management company in the US regarding data results that were not what were expected (due, it turned out, to different countries using different baseline laboratory values). In order to understand what was wrong long and lengthy discussions within the research sites took place to check over the test results and the processes undertaken to collect the samples, conduct the tests and input the data. This occurred on top of routine daily discussions between the doctors/ nurses, lab staff and data team that scrutinised each CRF before the data was entered into LIMS as well as day-to-day discussion regarding the progress and significance of lab test results between nurses and lab staff and amongst the lab staff themselves.

The focus on SOPs and forms creates a situation where it is possible to see the lab (perhaps in conjunction with the data management teams) as a central node within the clinical research site – and beyond within the wider IAVI partnership during discussions of clinical research data – as a result of its multiple interactions with others in the exchange of knowledge relating to clinical research information and data. The result is that it becomes a ‘stabilising force’ (Singleton, 1998) in its own right having the ‘situated’ knowledge (Lave, 1993 in Quintas, 2002) required to translate data from the blood sample to the form and the authority required to work out any ambiguities relating to problem data entries.

Examples of process knowledge and information exchange move beyond and outside the research site itself and do not only occur between staff within the clinical trial site. There is frequent discussion between the doctors/ nurses in the clinic and the community mobilisers, peer leaders and CAB members to gauge what was happening in the community within which the research trial site was situated. It was widely acknowledged that this knowledge was invaluable and wide-ranging:

> "I was just reading a profile that our Amsterdam office sent us of one of the community mobilisers in Kangemi and she came with not only a wealth of experience but she knew Kangemi community like the back of her hand and I think that there's not much we can add to that kind of experience and that kind of knowledge, maybe some of the content pieces for sure but I think its much harder to get the community perspective… in terms of knowing the community and how to engage them, its process and materials specific." [IAVI6]

The community mobilisers act as knowledge brokers through their activities as I discuss in Section 5.3 of this chapter in more detail. The role of community mobilisers here deserves special mention as they act not only as knowledge brokers but also as 'translators' (c.f. Pigg, 1995) of different notions of 'development', 'research' and 'healthcare' from the research setting into the community setting and vice versa with positive and negative consequences.

During my fieldwork I saw plenty of examples of where community mobilisers were regularly called upon to go into the community to find a volunteer who did not show up for a clinical trial appointment. Their knowledge of the community means that they are more able to know exactly where to find a volunteer when addresses are not always accurate and trial participants may not be at home. For example, on arriving at a trial site one morning I met two community mobilisers who were discussing the trials and tribulations of a visit to find a volunteer earlier that morning. One of the community mobilisers had gone out to a community early in the morning to find the volunteer who had not shown up for a regular check up the previous week. After driving around the community several times, she eventually found the volunteer and spent all morning persuading the volunteer, and more specifically, the volunteer's family that her illness (tonsillitis) was not due to the vaccine she had received and if it was that it would be okay because there were strict protocols relating to adverse reactions. The volunteer was persuaded to remain in the study and to attend the

clinic for her check-up appointment. This was a relatively simple case. In other situations, the community mobilisers had to call on their knowledge and skills much more intensively. When talking to a nurse at another site, I was told it took five attempts to find a volunteer who needed to be traced to receive a revised test result.

For others, working in a clinical trial setting meant they interacted with the wider community in which the site was based in new ways and gained greater understanding of the community and of different ways of life:

> "I get to learn new things every day. Initially I was working in Kilifi, which is a different setting altogether, that has a discordant couple [cohort] and it's a bit of a conservative society. But once I moved here to Mombassa I found it's a different kind of thing altogether. There are different people with different sexual orientations. I have been able to accept that and I believe they have been able to accept me…" [Kilifi7]

Finally, it is important to acknowledge that some staff have more knowledge than others and to be successful in developing the codified forms of knowledge that are the necessary outputs of the trial activities, this knowledge needs to be imparted. This again requires not only knowledge exchange but also learning opportunities to be available. The counsellor supervision sessions are a case in point of peer-to-peer learning that takes place. At the same time I saw examples of where those staff members with more experience in the labs or in data management, helped their less experienced colleagues. A data manager informed me:

> "…the staff that I currently have, they are not really very familiar with data transcription so I have to literally do most of the work, even after they have transcribed, I have to literally verify and make sure that everything is okay." [KEMRI9]

While, one lab supervisor in talking about the knowledge created in the labs told me:

> "OK, the types of knowledge that we create in the labs are much more technical aspects. If I have better training in one aspect of the assays and one of the technicians has a problem with an assay I can tell them how to troubleshoot and solve this kind of problem and what my experience is regarding this… So that's the kind of knowledge we are able to disseminate. Probably when we run quality controls and it doesn't pass, it's my job to see how that can be done and disseminate the knowledge and for them it's always a learning process." [KAVI7]

There were also other more general examples of where – for SOPs to be undertaken or understood, forms to be filled, and activities carried out – more routine shared learning through the discussion of experiences and knowledge took place. The strongest example of this was the weekly teleconferences that were held between lab staff at all IAVI's sites conducting similar trials. These are important opportunities for discussion and learning:

> "… because sometimes people talk about their experiences, it's being led by [person A]. They talk about their experiences and sometimes you have a problem on your site and through the tele-conferences you can be able to brainstorm and are able to learn something, what some other person has done." [Kilifi12]

Similar opportunities were found through other routine meetings (weekly team meetings at the research sites, daily discussions around the CRFs, supervision sessions etc.), email and telephone discussions but also the result of simply day-to-day exchange of information. For example when I asked a nurse counsellor about how learning occurred she told me:

> "…if it's the fellow counsellors, I really learn a lot, especially when we are sharing our day-to-day experiences, from the admin then we learn quite a lot because sometimes, you know, maybe I've just taken a file and something has just been picked and how come I didn't do this. And so if I didn't know it should have been done or it just happened, I should have done. And I learned that maybe the next time I'm going to be more careful. For the data too, I learned a lot because they come with those things too. Especially when they put it in the computer and it skips patterns, maybe I shouldn't have put something there or I skip some information that was vital and I should have put it there. So I believe it's like I've got something to learn. Community mobilisers, I learn from them, because it's them that give you feedback. Even on our own service… from our own service because we interact with the community and there was feedback through the community mobilisers, how are they handled for example when they came in, how did they [the volunteers] feel about our service." [Kilifi11]

Such interaction was seen as important for the creation of team work as exemplified by this quote:

> "… we are working together here. We interact in the sense of, maybe I might see a client and when I have done with that client I hand them back to the clinician, like that. Or if I may be having an issue, I go and talk to them and then sometimes also we have meetings… the most important thing here is the need for all the people who work here, the most important is their

> collaboration, that they work together and each one of us should know what the other person does, and should work together in a harmonious way." [Kilifi10]

It was also seen as a way of learning on the job when new. When I spoke to one of the doctors at KAVI she told me that when she was new to the job (and also to clinical trials) she had been introduced to everything by the nurses:

> "When I came in, I didn't have the experience, the doctor had just left and not all the time I had a nurse to guide me, but that's how I learned most things. I had my medical work and already I could treat and everything but how to do the research side of it I had to learn from the nurses. So, yes, there's a lot of teamwork and accepting that sometimes you may have to learn from someone who is much junior that you are." [KAVI16]

Teamwork and learning on the job were also seen as providing a way of gaining more general skills such as organisational, leadership and communication skills that are important for institutional processes to take place effectively. There are obviously implications related to an emphasis being placed on teamwork as this has the potential to change the leadership dynamics within the IAVI partnership and the clinical research sites more specifically. However, the majority of those I interviewed felt that the decision making process, particularly within the clinical trial sites, was still very top-down and hierarchical as noted in Chapter Four on collaboration. This in itself therefore potentially contradicts the idea that teamwork exists. However, leadership strategies and teamwork do not necessarily equate to the same thing. It is possible to have an organisation that thrives on teamwork in its work activities but which is managed in a top-down manner. Thus the doctor, while acknowledging her place within a hierarchical leadership structure, believed that teamwork was essential for success:

> "I believe I have gained a lot of unique experience that I would not have gotten elsewhere, maybe KEMRI, but they are still not doing an HIV vaccine, but I have gained a lot of research experience, specifically clinical trials. Also, experience in terms of I have had the opportunity to do managerial work, supervision, which is rare in a traditional medical set-up, doctors are usually not administrators and all that, but here it is inevitable that you have to do a lot of that. Things like, what a protocol is, developing a protocol. Basically doing research for clinical trials. I have had the opportunity to interact with people that I guess I wouldn't have within my restricted medical field, at meetings you know, researchers and people like that. I think the experience of working with people, the teamwork thing, it's quite different from what you can call teamwork in a medical practice, and realising that this kind of teamwork, you

> feel the traditional medical set-up under the doctor. I'm the doctor, this is my field, you are the nurse, you clear with me first of all, and I am the one who knows this area and this is not your area. That kind of thing is different, if you want to work in a team in research; you have to be very open-minded. If it comes to certain things like counselling, I may have the know-how but I know the nurse is best in that." [KAVI16; emphasis added]

5.2.2b Macro level capacity building

Alongside the implicit and somewhat obvious development of institutional capacity there has been a more overt emphasis placed by IAVI on the creation of macro level capacity in that it has worked to create an enabling environment supporting AIDS vaccine research activities in Kenya. This takes place both around the research setting through the creation of a research culture. It also takes place within a wider policy arena including the communities surrounding the research sites, the general healthcare community and the wider government related policy arena. I shall now discuss each of these in turn.

Institutional capacity building opportunities created, as mentioned a little earlier in this chapter, the building of a greater understanding of the research process by those involved and a furthering of a research culture within the area of vaccine clinical trials. There is a feeling amongst those involved in Kenyan AIDS vaccine research that "we've got the brains, sometimes what we need are the bricks to build this [local capacity]" [IAVI5]. The formation and strengthening of a research environment and culture is an important aspect of such macro level capacity building activities.

Although few had been involved in clinical trial or vaccine research before, it was felt by most of the doctors and nurses I spoke to that Kenya did have an existing knowledge base to which IAVI has added systems and infrastructural support enabling Kenya to gain an international reputation in AIDS vaccine clinical research. KEMRI, as outlined in the introductory chapters, was established in the late 1970s and since that time has been conducting high level clinical research particularly, but not exclusively, in the area of malarial illness, treatment and prevention, benefiting from partnerships with the UK's Wellcome Trust and the US Walter Reed Medical Institute. KAVI was established on the back of a collaboration between the

University of Nairobi and the University of Oxford around the identification of HIV as well as other international research collaborations for example with the University of Manitoba. The result was an existing base of expertise:

> "We may be fortunate here in KAVI to have previous studies that focused heavily on training. And so IAVI has probably come in when the capacity has already been done by other researchers that came to Kenya a little earlier, like the Canadians. And so the majority of those who are here now are benefactors of other studies that had a very strong research training component. But I think for purposes of posterity probably it would be important that we see that the majority of those who are currently at the helm of research in Kenya are probably people closer to retirement I would say. So there is a need to have younger people positions to take over responsibilities. And it would not happen if there is not a training facility." [KAVI10]

While acknowledging the existence of existing expertise the pharmacist quoted above also pointed to difficulties IAVI and others have faced in collaborating with Kenyan institutions in clinical research activities, due to capacity issues, similar to situations found elsewhere (Nchinda, 2002). In our discussions the pharmacist highlighted the existence of weak education systems with few resources and a lack of emphasis on research activities. Although there is an existing base of senior researchers who had some clinical research experience, many of those working on IAVI projects in Kenya as mentioned briefly earlier have never been involved in clinical research before, coming out of the regular healthcare system (as doctors or nurses) or from science departments of the universities where research was not taught. As one doctor put it:

> "I keep wishing I had realised [the importance of research training] earlier because a lot of us leave medical school and the only speciality we know is clinical – be a gynaecologist, be a… - and the boring one is public health. That's how it is in medical school…" [KAVI16]

The result was a need to put in place the systems and infrastructure and ensure sufficient training was available for those new to the area to enable clinical research to take place. There was confidence that skills could be added to the existing knowledge base once systems were in place. This in itself was not seen as being a way to necessarily stop potential newly qualified staff from looking elsewhere (particularly abroad) for work although increasing the number of opportunities was seen as the first step to curbing such 'brain drain'.

One IAVI member saw the role of IAVI as one of creating opportunities and systems: "I think IAVI really can bring a degree of operationalising and systematising to the kinds of activities that take place at the sites." [IAVI6]. Similarly, an older member of KAVI told me that this created the opportunity to learn new skills:

> "Even me, although I had participated in other clinical trials which where smaller than these vaccine studies, this has bought me to a new level of knowledge in terms of how to conduct clinical trials. And it's quite challenging because in this research set up you need to document everything you are doing." [KAVI3]

In particular, GCP training provided by IAVI was seen as creating a situation whereby the sites were now at an international standard and that the sites are able to "run their own show".

The result has been the creation of national pride in the country's AIDS vaccine research activities and the strengthening of a research culture amongst those involved. Those working in the area in Kenya talked about "learning to take research seriously". I saw numerous examples of where staff came in early or stayed late to finish work, actively engaged with the literature and issues of clinical research through the creation of a journal book club at KAVI and the attendance of research seminars at KEMRI in Kilifi. There was also obvious trust that the skills and expertise existed to conduct research activities between IAVI and the research sites (for example, IAVI no longer maintained a permanent presence at KAVI) and between senior and more junior staff members (exemplified by who was authorised to sign off data and quality control forms).

Many I spoke to at the research sites talked about being able to develop a career path in clinical research and wanting to develop their skills themselves even when there was no outside help. I was given information to suggest at least six people from KAVI and the KEMRI IAVI project were paying for and undertaking further academic study in their own time and using their own funds because they saw a career trajectory for them in clinical research. Although there was some disquiet as to the future of KAVI or KEMRI's IAVI project should IAVI funding finish, most

were confident that these centres would remain and that other centres were already involved in or were also starting to conduct vaccine research in the country. Unfortunately, I also was also told of examples of at least two staff moving to other research sites once they were further qualified academically and had gained some career experience in clinical research. This was seen as creating a 'Catch-22' situation whereby sponsoring further academic study did not necessarily guarantee added value for IAVI or the research centres. In the converse, KEMRI's IAVI project had benefited from gaining at least two staff with clinical research experience obtained while working for another clinical trial project in the country.

A further example of a growing research culture, through the development and movement of expertise, has been the use of KAVI as a showcase to other research groups wanting to conduct AIDS vaccine trials. In these situations, their staff act as knowledge sources for other clinical research sites. I was told of how KAVI staff have provided advice and expertise to other sites and how workshops and seminars where held at IAVI sponsored sites to which other research groups were invited.

An emphasis is also increasingly being placed on the strengthening of local healthcare services in the research site communities particularly in relation to ensuring a strong referral pathway for trial volunteers regarding HIV/AIDS testing and treatment facilities. The integration of the research and care components is strongest in the IAVI project at KEMRI due to KEMRI's long history working with the District Hospital in Kilifi. As one of the hospital's managers told me:

> "It has been successful lets say because of the linkages between the research component and the care component. And the research component actually is more interested in identifying (depending on which research they are doing) it's more geared towards prevention. So, for a public health concern, that comes in handy. And two, there are some research protocols that's related more in picking the HIV negative and the HIV positive. But in the course of so doing then we find that patients who are identified as HIV positive are actually enrolled into the care programme. So the integration is good at that level. Then, number two, at the level of the clinic, there is also very good element of integration in terms of personnel, although this is not constant, it keeps on changing, and that's something that we need to iron-out to ensure that care and research run smoothly." [Policy11]

The strength of this integration is due to IAVI's funding of the building of the CCRC, an integrated research and care facility in the middle of the Kilifi District Hospital. In a similar manner, in Nairobi IAVI is working with the City Council to arrange for a permanent supply of ARVs at the health clinic in which the research site is based in Kangemi.

The IAVI partnership's activities are therefore leading to the creation of macro level capacity building in the form of the creation of a national research culture and research systems including support of related healthcare provision activities. At the same time, other forms of macro capacity building have also taken place as a result of IAVI's own emphasis on building a stronger policy arena for AIDS vaccine research in Kenya, regionally and internationally. This includes focusing on building more local policy support within and around the communities in which trials take place. It also involves building support within important stakeholder groups such as civil society organisations and healthcare practitioner communities. This also involves building support within the government related policy arena.

As such, IAVI understands the importance of building an enabling environment within which research activities can take place. Their Country and Regional Programs (CRP) department's role, and a mandate of the regional office in Nairobi, is to work with the research sites and others to conduct community education with communities within which the research sites are situated and with the wider community of healthcare providers and policy makers in the country.

A member of an NGO working with IAVI to conduct this training informed me that it was important for public risk perceptions regarding vaccine research to be reduced and for this there was a need for civil society organisations to get involved as it was important for IAVI to support "not just biomedical research" activities. Thus IAVI has a role, as the quote below highlights, to build a stronger enabling environment both at the community and policy levels:

> "First and foremost, communicating with communities is a real challenge to get them to participate in the vaccine trials. But also if you look at what we went through in the initial stages to get the policy makers to accept and

> approve the studies, you get the impression that this is a task, it is not a one in a lifetime event – its continuous and needs maintaining the tempo." [KAVI3]

What the NGO representative and the KAVI doctor were referring to is the importance IAVI has to put on reducing the stigma and negativity attached to HIV/AIDS research activities, particularly the issue of incorrect and difficult media reporting as part of their efforts to build an enabling environment. IAVI is working with the research sites and with stakeholders within the wider AIDS vaccine research community to conduct these activities. An example of this negative press is the cartoon in Chapter Four which portrays a scene of a local township community inundated with research staff and others all vying for control of the AIDS vaccine research resources. The unenthusiastic or negative attitudes towards clinical research in African communities due to previous encounters with researchers, poor understanding of disease or the research processes together with local attitudes and beliefs has been documented elsewhere (c.f. Fairhead, Leach, et al., 2006).

In light of this and first hand experience of negative publicity (as per the cartoon illustration) IAVI spends time developing materials, conducting training with the support of local NGOs, and engaging local healthcare practitioners and others in discussion of the pros and cons of AIDS vaccine research. In describing the activities one of IAVI's staff explained them as follows:

> "We have a couple of different initiatives, one is to engage civil society and the other is to engage healthcare providers… Both of these initiatives are being undertaken in what we consider are high priority regions in Kenya, and in both of those exercises we're including the PMOs [provincial medical officers] and the PASCOs [Provincial HIV/AIDS Coordinators] and all those for the district and provincial level administration. So that's the mechanism that we would use there…
> … In my opinion they've gone very well. There's certainly a lot of interest and the organisations that are kind of our entry points into those provinces they are very keen on continuing the exercise. The NGO effort began first and we just did a mid-level evaluation and at the end of next year we'll do an end-line evaluation and we will be able to see what kind of impact they've actually had in terms of building awareness and education of staff in NGOs in those provinces. But, anecdotally, it does look like it's been a really positive programme that people have become very interested in and we've relayed quite a bit of information. There's been a lot about collective learning there as well." [IAVI6]

This 'vaccine literacy' work, as it is termed by IAVI, is a further layer of work to that which occurs immediately around the trial sites overseen by community mobilisers at the sites (with support from IAVI) and through the network of peer leaders and the activities of the CABs. At the community level the emphasis is on building understanding, awareness and support amongst the local community within which the research site is situated which will also assist in the recruitment of trial volunteers. Most of the work is focused around regular community meetings held in local community centres or in the open air that are attended by anything up to (and at times over) 100 people. At these events, research site staff give talks about HIV/AIDS as a disease, the A-B-C (abstinence, be faithful and use a condom) of prevention, why vaccine trials are important and how they operate. These interactions with the community are not a one-way flow of information but provide an opportunity for the community mobilisers to see what is going on within a community and hear people's opinions towards the research. As one peer leader described to me:

> "My main task first is to link the research team and the community. The other thing is that we disseminate the correct information about the vaccine. The third one is about recruitment. We the peer leaders are the people who recruit on the ground for the volunteers to come forward to be given the vaccine… I bring out the questions the community asks…" [KAVI12]

An emphasis has also been placed on building a stronger policy environment within government circles around the AIDS vaccine research activities. IAVI has supported the development of a national HIV vaccine research sub-committee and the development of research guidelines by this committee to provide a regulatory pathway for all vaccine research. One IAVI member of staff told me that initially when the first vaccine trial had taken place there was no regulatory pathway in place and approval for the trial took nine to 10 months. Now, seven years later in 2006, it took just two to three months. She stated this was partly because a regulatory pathway was now in place but also because vaccine research had become a source of national pride particularly as the first vaccine (developed jointly by the University of Oxford and the University of Nairobi) had been seen as a national product. Others also reiterated this informing me that the Government of Kenya had seen its ability to become a centre of excellence in (AIDS) vaccine development and as such the

Government was particularly supportive to the activities and requirements of vaccine clinical research organisations.

However, despite this there was a perceived lack of political will and unified approach towards clinical research in the country. There was some acknowledgement, both by those working in the area of AIDS vaccine research and those working in the national health policy arena that I spoke to, that research was not high on the political agenda. Treatment and the provision of ARVs were seen as being more important when it came to developing national HIV/AIDS policy while the universities were unable to invest in strategic research activities. I was also made aware of a lack of unity both nationally between research stakeholders but also at the level of the research sites. When discussing the issue of national research policy I received a picture of a diverse set of national AIDS vaccine research stakeholders who all fought their corner to solidify their own positions before working together as a team to ensure research received more than a cursory mention in national policy documents. No common reasoning was given for this but I understood the reasoning to be around different stakeholders wanting to retain, regain and justify their own positions and existence in terms of funding, reputation etc.

More widely, IAVI is involved in the stimulation of a regional and international discussion of an AIDS vaccine research agenda. IAVI staff work with African governments and the African AIDS Vaccine Programme to develop National AIDS Vaccine Plans and work to ensure that AIDS vaccine research does not get left out of regional and international policy discussions and related documents. For example while I was in Kenya the regional office sent staff to Abuja to work with health ministers writing statements at UNGASS (the UN General Assembly Special Session on HIV/AIDS). Furthermore, IAVI lobbies the East African parliament and national parliaments, workshops have been held in New York with WHO around vaccine regulation and IAVI's senior management are involved in international level debates around the financing of health research for neglected diseases.

5.3 IAVI 'doing development without doing development'

The above section has highlighted that as a result of IAVI's partnership with KAVI and KEMRI and others in Kenya, skills have been increased and resources provided to assist AIDS vaccine development activities in the area of clinical trials. Much of the overt capacity building activity – what was defined as capacity building by those I spoke to – was traditional tangible provision of skills and resources. However, in undertaking their general research activities and their associated capacity building (training and infrastructure resource provision) forms of process capacity have been created. Collaboration activities have taken place and these in turn have led to other forms of process capacity building such as the nurse counsellors learning on the job and enhanced ARV provision within the trial sites. This highlights the difficulty of trying to disaggregate the capacity building activities into categories. One of the reasons for this, as I shall discuss in this section, is that IAVI has had to do capacity building and has had to conduct some forms of process capacity. Thus IAVI in its activities has placed a focus on process. However, as I shall now show, this is as a consequence of needing to ensure AIDS vaccine development activities take place. Thus IAVI has not put an overt focus on building some forms of process capacity even though it has conducted or promoted the conduct of such activities by others. This is particularly true of institutional level process capacity which is based on the promotion of collaboration, linkages and knowledge exchange. In the area of macro level process capacity building IAVI has been much more pro-active. I will now discuss the implications of this and how the result is that IAVI ends up 'doing development without doing development' (Chataway, 2005) whereby it conducts activities similar to those of an international development organisation but not as a result of an overt strategic decision to act in such a manner.

One of the reasons for this lack of overt focus on process capacity, particularly institutional level process capacity building around the building of linkages and knowledge exchange, is due to a tension as to the degree to which IAVI's partnership activities should focus on capacity building activities. Often such activities are seen to detract time, energy and resources away from the day-to-day activities necessary

to achieve the partnership's ultimate output and goal of developing an effective vaccine.

This tension was highlighted most significantly during my discussions with one of the PIs I talked to. When I first met him I was very impressed by a statement he made that capacity building was "more than just having a good office and GCP training." He acknowledged the importance of building staff skills in critical and analytical thinking so that when things go wrong they know what to do and feel responsible for ensuring things go well. His feelings matched my ideas that the IAVI partnership provided an opportunity to leave something behind that was more than a set of buildings and staff without guaranteed career options. In working with UNICEF in a past life I was well aware of situations were 'programmes' or 'projects' had, for instance, spent money training staff in motorbike mechanics, given them motorbikes and left them to run rural health projects without the support and understanding of what was needed to make the venture viable – to mend the bikes over the long-term, to keep drug supplies maintained etc. My initial discussions with this PI highlighted that it was possible to see the IAVI partnership as providing an opportunity to build capacity of more generic competencies. Their capacity building activities moved beyond sustainability defined in terms of absorption, adaptation and embeddedness of external processes, to the creation of problem-solving capabilities that create 'learning institutions' (Senge, 1990) with the generic capacity to tackle other issues than the one IAVI was initially set up to do (Hawe, Noort, et al., 1997).

In a later discussion however I found his views were not so clear cut, or rather, that the capacity building activities of the IAVI partnership take place at various levels with different goals depending on who is discussing the matter and in what context these discussions take place. We were discussing the initial results of my research which I had distributed in advance of my last research trip to Kenya in November 2006. In particular we were discussing the results relating to how capacity building activities were delineated, defined and encouraged. His response was to answer with the question, "What should the end point be?" He outlined how sentiment in IAVI had changed over time with support for formal academic training lessening as an

increasing focus was placed on trial specific short courses and workshops. The focus throughout these activities was on the end point; the need to ensure that service delivery (the successful completion of a trial and ultimately the development of a vaccine) took place. He wanted to know whether I felt this was wrong. Should the end point be something else? The project is a research project first and foremost, he said, and as such all capacity building was geared towards this and the focus changed as was required at different stages of the research project's development. He stressed that currently (November 2006) that meant training was focused on trial specific activities. In relation to the more macro level capacity building activities and in particular the integration of research activities with healthcare provision, he was also pragmatic. The bottom line was that it all came down to what was necessary for successful project delivery. This meant that at the time of our discussion the focus was on research activities - "it's a research related project" and as such activities were conducted in this context. However, in order to do their work they had in the past focused a significant portion of their time on healthcare provision activities because a referral pathway was required for trial participants.

My discussions with this PI highlight how complex the IAVI partnership's relationship with capacity building is. Despite a lack of overt attention on the importance of knowledge exchange and capacity building being seen at the most extreme as a by-product of general work activities, it was possible to find staff that did recognise the importance of knowledge exchange and thus a focus on process capacity building. I did find some recognition within IAVI that knowledge exchange is important even though this may not be acknowledged or utilised sufficiently. For example, one IAVI manager told me:

> "I think something we need to build on is actually exchange of knowledge between the sites. We are starting that, mainly, in counselling. But also in recruitment strategies where sites are similar and are looking at similar populations. And actually in Kenya, the two epidemiology sites are working with similar populations and so we're starting to work especially in counselling to have exchange visits with counsellors. But the majority of the exchanges actually happen in the training programmes we have and the investigators meetings when everybody comes together. And I know that they all find that helpful. The study physicians chat with the other study physicians and the nurses and its something that works well in the labs. The lab teams because they, I think they have joint conference calls and also have joint training

> sessions, even just the GCP courses that we run. It's not just the course but it's their opportunity that they get together. And it's great because then we know that they email each other. You know if Kilifi lab has a problem the first thing they do is ring [KAVI] not necessarily us. So, I guess there is a lot of exchange of knowledge that I don't really notice a great deal…
> … so learning from each other's experience rather than this is the rule, you know, everybody learns the rules but how to actually implement it and how to, you know, in fact we've been talking together. [A colleague went] to Kilifi yesterday and so we're hoping to get one of the counsellors from Kigali there because they've been doing it for 20 years. Let's not reinvent the wheel. So yeh, its, its about sharing experiences." [IAVI2; emphasis added]

There is an understanding amongst some of the partners at least that knowledge is important and IAVI provides a linkage point in brokering that knowledge. One lab supervisor informed me, "I think that's one of the main objectives of IAVI; to link all the sites." [KAVI7]. This is an example of where there is also an understanding by other partnership members that knowledge management and the building up of absorptive capacity (an understanding of the value and use of knowledge) is one of IAVI's functions.

I mentioned earlier in this chapter that development organisations have seen capacity building as a deliberative action to be undertaken in development projects (although not often to the extent of building generic competencies). IAVI however is not your typical development organisation even though it was borne out of the international 'turn to partnership' that was seen as a way forward for more successful capacity building to take place. As outlined in the collaboration chapter, IAVI works much more along the lines of a private sector company, it acknowledges the use of a virtual pharmaceutical company business model. The result is an emphasis on results and end points – the successful completion of contracts and projects.

Thus capacity building although acknowledged as an activity to be undertaken is not given prominence more than as is required for activities towards development of an effective vaccine to progress. As a result, certain levels of capacity are focused on more than others. Individual level training and infrastructure support dominate over all other types of capacity building. While there is some focus on macro level capacity building, institutional level capacity building focusing on the building of

less tangible organisational, learning and knowledge based connections appears to be neglected. Such meso level institutional capacity building occurs but is not a focus of capacity building activities per se. It occurs as a consequence of what is required in order for work to get done. For example, the teleconferences between labs were not set up as an overt attempt to build capacity but in the recognition that for work to take place such interaction between lab managers and technicians was needed so that work was not duplicated and problems solved faster.

The lack of attention to institutional level analysis has been documented more generally within efforts to build capacity development:

> "The shift in emphasis from the micro level (on the individual) to the macro level (on national institutions) has left meso level (organizations – especially public service delivery organizations) neglected and thus vulnerable. This current model generally assumes that if you train people and get the legal and market rules and regulations right, organizations will take care of themselves." (Horton, Alexaki, et al., 2003: 32)

The lack of attention towards institutional capacity by IAVI appears to be at odds with the increasing importance attached to knowledge within health innovation and research circles. In fact, health research capacity strengthening was deemed important in recognition of the fact that society is contextualised around knowledge and that the economy is based on who has what knowledge (Neufeld and Johnson, 2001). Investing in health "research (as a basis for knowledge production) assumes even greater importance… it is more than just a strategic tool for effecting improvements in health; it is now the driving force behind all development." (Harrison, 2001: 45).

The lack of attention on this form of process capacity is related to the focus of current donor and international development strategies on outputs and tangible results. Just as there is a tension within the IAVI partnership regarding the type of organisational model to focus on, there is also a related tension internationally between focusing on long term sustainability over short term results oriented approaches. Thus despite, as outlined in Chapter Four, some within the development sector having shifted their emphasis from a supply-driven technical assistance based

approach centred around the 'donor vs. recipient' relationship to a networking and partnership approach including demand-side (community and user engagement) concerns focusing on sustainability much of the current work on capacity building focuses on performance towards goal attainment (Milèn, 2001). As outlined above in Section 5.1.4, process orientated approaches are often being ignored.

Studying IAVI's approach to capacity building, as I have done above, highlights the difficulty of moving on from notions of capacity building as development assistance (of donor-recipient relations) and the supply side requirements for programmatic success. The consequence of retaining such an approach is an unequal partnership – what I termed in Chapter Four a parental partnership – with uneven levels of knowledge and therefore power; where who benefits and who controls the activities on a day-to-day basis is highly complex and difficult to determine (Velho, 2006). However, despite this, the IAVI partnership is not necessarily a 'bad' collaboration because it does inadvertently place an emphasis on the importance of knowledge. It therefore does not only build individual capacity and macro capacity but also meso institutional capacity. Even though these are not championed as important outcomes in themselves the result is that the IAVI partnership works towards some form of health research capacity strengthening.

In order to move towards demand-led activities and increased networking, attention is required to move beyond focusing on goal attainment and towards the gains to be made from focusing on process capacity at the meso institutional and macro enabling levels. It is widely accepted within the innovation literature that although collaboration and knowledge exchange will take place as a natural activity because it has to (sic, the teleconference example above) innovation's potential will only be recognised if such knowledge exchange is encouraged and promoted (Carlsson and Stankiewicz, 1991; Clark, 1985; Johnson and Lundvall, 2002; Lundvall, 1995; Narula, 2003). Focusing on meso and macro level capacity through the creation of organisational, learning and knowledge based connections will build generic competencies (Hawe, Noort, et al., 1997) and a learning function (Morgan, 2003) in order to do more than fix problems that arise in working towards goal attainment.

In particular, the IAVI partnership in Kenya could be seen as providing an example of the role of what is termed 'absorptive capacity' in innovation theory or, as outlined in Chapter Two, the ability of a firm to successfully acquire, assimilate, adapt and utilise knowledge acquired from external sources (Cohen and Levinthal, 1990). This term can be used in the discussion of PPPs to describe the capacity of a partnership to manage knowledge (Hanlin, 2007). The IAVI partnership is not a firm but IAVI, as the central node within the partnership operates similar to a virtual pharmaceutical company, effectively managing and manipulating knowledge between the various partner organisations.

As discussed briefly in the last chapter, because IAVI works in ways similar to a virtual pharmaceutical company, it is possible to consider the role of IAVI as both a knowledge broker and integrator in relation to its activities and the workings of the partnership (Chataway, Brusoni, et al., 2007). IAVI also acts as a knowledge broker in that it manages a diverse range of stakeholders each with different forms of knowledge that other partnership stakeholders need. Chataway et al argue that this is particularly true of IAVI's advocacy work. IAVI acts as an integrator in its vaccine innovation activities by not only contracting out research activities but manipulating knowledge internally, particularly through its advocacy activities, so that it can be more effectively used by others at different stages of the innovation chain. Chataway et al contend that although IAVI does not call itself a knowledge broker or integrator, its ability to understand the value and use of knowledge are strongly evident in its activities internationally.

My PhD research shows that this is also the case in terms of the IAVI's activities at a country level in Kenya where there is a creation of absorptive capacity within the partnership as a result primarily of IAVI's knowledge management activities. IAVI, without realising it, places an emphasis on knowledge which works to strengthen the linkages between those involved in the partnership. This occurs in two ways.

Firstly, IAVI is aware of the importance of ensuring knowledge transfer and communication at the country level. IAVI sees the importance of training workshops as an avenue for information exchange outside of the formal teaching that takes place. Similarly, while it encourages peer-to-peer learning having set up teleconferencing activities between lab staff around the multi-site studies it places less value on this. Yet it works strongly to create understanding and awareness between those involved in the communities surrounding the trial sites and at the policy level.

Secondly but less obviously, the activities and procedures put in place by IAVI at the research site – its "systematising and operationalising" activities – have created a situation where multiple knowledge brokers exist and where knowledge brokering and transfer take place on a day-to-day basis. For example, as part of the study I asked 25 people who worked in the research sites to map their day-to-day knowledge flows as a means of assisting my discussion. The maps helped articulate different interactions and bring out details of with whom individuals talk, discuss with, learn from, pass information/knowledge to and what form this knowledge/information takes. These maps (an example is available in Appendix 5) provide an overview of the complex network of interactions as well as the knowledge and information flow that occurs within a certain section of the IAVI partnership (around the research centres). PIs act as knowledge brokers between IAVI and the research centre staff providing the link by which study progress is passed to IAVI and new notifications of training, changes in protocol etc. are notified to staff. The lab technicians act as knowledge brokers between the data (the samples) and the doctors/ nurses being able to explain what the data says (what knowledge the samples hold). Finally, the community mobilisers act as brokers of community held knowledge to the research sites and of 'scientific' knowledge to those outside the research sites.

The IAVI partnership at country level in Kenya therefore does not appear to overtly focus on building institutional capacity at the meso level but does however conduct such activity. In the same way other forms of capacity building more generally occur, institutional capacity is created as a result of working towards study progress;

as part of the process towards goal attainment. As one member of IAVI's staff told me:

> "You need someone to be able to support the training etc. You can't just walk in and do a trial. The staff have to have lots of training and establish all the procedures etc. Someone else could have done it… any other group. All the other groups working in the developing world would have to have the same, you know, process. There is nowhere in the world that if the person hasn't done a clinical trial before you send them the protocol and say, 'could you let me know when you have the data'. I mean, it doesn't work that way because good clinical practice, as you know, there are requirements and there are the requirements of the investigator but there are also the requirements of the sponsor. So basically, we are just doing the same as we would in any country, we are going in and making sure you are covering all your responsibilities to conduct the research." [IAVI2; emphasis added]

The result is that IAVI can be said to end up 'doing development without doing development' (Chataway, 2005). It has characteristics of an international development organisation – which has the goals of capacity building, sustainability and integration – when it means to be an efficient business based model of partnership. This tension is accepted within IAVI but also acknowledged to cause problems, as will be discussed in the next chapter. An emphasis is placed on what is needed to arrive at the end point – the development of a vaccine. The process taken is less important. The result is that capacity building is seen as an input and not an important end in itself, despite what actually happens inadvertently in terms of institutional meso level capacity.

Should IAVI choose to focus on capacity building more overtly, particularly on meso level institutional process capacity, this would open up an alternative means of evaluating the success of the partnership. Focusing on outcomes rather than outputs and impacts may be useful for partnerships such as IAVI for two reasons. Firstly, this makes sense practically as focusing on building institutional capacity creates the learning function that organisations need to build the generic competencies for true sustainability. This is particularly necessary as working towards goal attainment does not happen in isolation of the social processes in which activities occur (Mosse, 2005). The result is that for partnerships such as IAVI to "operate efficiently and effectively, they need to learn to adapt and change if they are to survive and

prosper." (Horton, Alexaki, et al., 2003: 37). Secondly, it also provides a means for an organisation such as IAVI to work out the tensions of its development sector origins and objectives with its efforts to work using a private sector business model.

5.4 Linking innovation and health activities using capacity building

One of the major implications of focusing on building meso level institutional capacity is that it emphasises the way knowledge is exchanged and how linkages are made between those involved in scientific research or innovation activities and those involved in healthcare activities. My research of the IAVI partnership in Kenya outlined above highlights examples of where these two fields of activity, which are often viewed in separate spheres of policy and practice, are in fact heavily interconnected. My research clearly shows how these two areas of research and healthcare are inseparable and need each other in order for AIDS vaccine clinical trial research to take place. As such, I will now outline examples of this interconnectivity before discussing the implications of this on the way the IAVI partnership is conceptualised and how this fits into a wider discussion regarding the definition of health innovation and how it is promoted that was introduced in Chapter Two.

In this chapter I have given a variety of examples that highlight the interconnectivity between those involved in scientific research activities and those involved in healthcare provision in order for AIDS vaccine development activities around clinical trials to take place in Kenya. First, I have highlighted the need for discussions to take place between research and non-research staff particularly those involved within local communities around the trial sites. This is because in order for clinical trials to take place, there is not simply a need for scientific knowledge or lab based knowledge but also a range of other knowledge that relates to promoting the trials, gaining understanding, enrolment to the trials as well as promoting HIV/AIDS prevention activities alongside the clinical trials.

Secondly, this chapter (and Chapter Four) has highlighted how although necessary, the interaction between those involved in scientific research and healthcare has increased as a result of the IAVI partnership activities in Kenya. Not only has IAVI's activities in Kenya created an interaction between those involved around the trial sites from these different fields of activity but it has also led to the creation of a wider AIDS vaccine research network. This has increased understanding of research activities within the local population living around the research sites and in the country more generally. The creation of this wider country level AIDS vaccine research network, which could also be termed a form of partnership, was not in existence before. IAVI's policy and advocacy work through its regional office have assisted in the creation of an HIV vaccine sub-committee (discussing regulatory and ethical issues of vaccine trials for example) that is the nodal point around which this wider network coalesces and operates from.

Thirdly, not only is there greater interaction between those involved in healthcare and research/ innovation activities around the trial sites there has been a cross-over of activities too. The research organisations, KAVI and KEMRI-CGMRC's IAVI project are now getting involved in healthcare activities. They are working to strengthen healthcare facilities because they need stronger referral pathways as part of their clinical research activities. Where possible, as I have explained, the research sites are trying to do this in partnership with existing care providers. However, at times, they have set up their own care provision facilities in the short term as their local public healthcare facilities become resourced, usually financial and infrastructure support from donor agencies.

Thus, these examples highlight the importance of communication between scientific researchers within and around the trial sites, healthcare providers and others within the wider country level AIDS vaccine research network. The activities of one trial site can not occur in isolation within the confines of 'science' or 'innovation'. The walls around clinical research have to be broken down. Successful innovation requires more than simply the training up of scientists or even knowledge exchange

and collaboration between scientists around trial sites. It requires the recognition of a wider range of actors from community members to legislators and regulators.

This has implications for the way the IAVI partnership is conceptualised. Recognition of these linkages emphasise the difficulty of separating research and care activities and how it is important, therefore, not to define health innovation simply in terms of R&D; in terms of what it takes to get a product produced. It is also important to consider the wider players and processes that are necessary for ensuring successful health innovation. The IAVI partnership in Kenya highlights how health innovation activities involve an interaction between actors from these two different arenas that is more than simply seeing healthcare practitioners as receptors of a new health product. They are in fact integral to their development; being part of a wider and interconnected health and research innovation system. Innovation of a new product must be seen through a wide lens that takes into account all aspects of a product's development including all the actors' interconnections from a diverse array of arenas who all at some point influence the scientific and technological trajectory of a product such as an AIDS vaccine (Metcalfe, James, et al., 2005). The starting point for moving towards such an inclusive approach is to bring together, as discussed in Chapter Two, the different starting points of these two different arenas of health(care) and innovation and their respective policy prescriptions.

Wider definitions of 'health innovation' by Morel and 'health research' by WHO and the Global Forum for Health Research outlined in Chapter Two allude to this need to be more inclusive. They stress not only product development but also the wider enabling policy development. However, as evidence from the IAVI partnership in Kenya in this current chapter validates, it is difficult to ensure a more inclusive approach focusing on the whole product development process is promoted even if it may be happening on the ground. As the next chapter will discuss, this is hindered by, a current emphasis on the end point; by a focus on goal orientation and a desire to get products out. The focus in this case is on capacity as access to products rather than a more holistic approach. Such an approach would consider the strengthening

of longer term capacity and building of linkages between the wide range of stakeholders that need to be involved to create sustainable capabilities.

Focusing on the need to look holistically at all the actors involved and the type and form their connections take is similar to the emphasis placed within innovation systems on the importance of collaboration and knowledge exchange which I introduced in Chapter Four. However, the difficulty of ensuring within the Kenyan IAVI partnership acknowledgement of these linkages and who is involved highlights the difficulty of identifying where the boundaries of such a system are. This further highlights the requirements for, but difficulties associated with, innovation systems thinking that is being used to promote PDPs such as IAVI and from which the concept of health innovation systems was developed. As IAVI's activities have developed over time in Kenya so the actors it has interacted with has changed. As has been outlined in Chapter Four while initially the partnership consisted of IAVI, the research organisations and trial site communities, it has since broadened out, partly through the creation of a wider country level AIDS vaccine research network including regulators, wider health care providers, government ministries and donors.

This is where marrying innovation systems ideas with thinking from within the anthropology of development field raised in Chapters Three and Four is relevant. At the end of Chapter Four I outline how Clark argues that innovation systems are viewed not as a concrete policy tool but should be used as metaphors for how innovation can be more successfully conducted. Such a perspective, when added to an in-depth and critical analysis of power and politics flows from an anthropology of development perspective, creates a focus on the whole process of innovation and all the actors involved and not simply on getting products out; on goal orientation and the end point. Such a perspective, used in this chapter, has for example highlighted the interconnectedness of actors from within innovation and health in the area of AIDS vaccine clinical trials research in a way not acknowledged before. In particular, it has highlighted the high degree of knowledge exchange and learning that takes place between actors within these two fields of activity and the importance

this has on ensuring successful achievement of activities and the building of longer term capabilities.

5.5 Conclusion

The previous chapter (Chapter Four) introduced the complexity of the IAVI partnership and, in particular, how it works in a different way at the national level in Kenya than as a global entity. One of the activities that results from the IAVI partnership, in Kenya, is the creation of increased capacity to conduct clinical vaccine research. Capacity building activities have been the focus of this chapter and therefore this chapter has addressed the research question around my third thesis theme. There is some acknowledgement within IAVI and its partners that this is an important activity of the partnership. However, the emphasis placed on building long term capacity is at odds with the demand to conduct clinical trials. The result is an emphasis on building capacity through training related to the conduct of immediate trials rather than professional development and academic training. This appears at odds with a current international health policy focus on the importance of working to strengthen national level health research capacity and relates to the way the IAVI partnership in Kenya fits within wider discussions of the usefulness of international development activities as capacity building opportunities.

However, while placing an emphasis on training and resource provision, IAVI does strengthen health research activities in other ways. In undertaking clinical trial research in Kenya the IAVI partnership activities builds what I term 'process capacity' by strengthening institutional processes at the meso level and the macro enabling environment. In not overtly acknowledging process capacity, particularly meso level institutional capacity around knowledge exchange and collaboration, IAVI has ended up 'doing development without doing development'. This is partly due to a tension existing within IAVI, and the partnership in Kenya more generally, between focusing on endpoints or the goal of developing a vaccine and focusing on building sustainable long term processes. This mirrors the tensions within

international development, outlined in the earlier section of this chapter, regarding different forms of capacity building that can be promoted. I will discuss this tension in more detail in the next chapter.

The discussion in this chapter has highlighted the linkage between innovation and healthcare actors and activities as a result of the knowledge exchange and collaboration that takes place. This chapter therefore also addresses the second theme of this thesis regarding collaboration's impact on the linkage between innovation and health. The recognition of the linkage between those two sets of actors is rarely acknowledged but appears, certainly in the case of AIDS vaccine research in Kenya, to be important. In particular, the discussion regarding which actors should be involved in the innovation process led me to discuss further the issue of innovation systems thinking introduced in Chapter Two and discussed in Chapter Four. As I state in Chapter Four IAVI is put forward as an example of a health innovation network, a form of innovation system. However, the activities of the IAVI partnership in Kenya I have described highlight how it fits into other alterative innovation systems as well: a wider AIDS vaccine research network and a health system. I argue that understanding this multiplicity is only possible because I have used a combined interdisciplinary approach that mixes an anthropological rationale with innovation systems ideas.

Chapter Six

Situating the Kenyan IAVI partnership:

Beyond partnership for health and innovation capacity

Both of the previous chapters have inadvertently discussed the turn to partnership in slightly different ways. Chapter Four started with arguments for the rise of PDPs from the premise of a business and market approach while Chapter Five emphasises an alternative approach to partnership focusing on development and participation. Thinking of the 'turn to partnership' as occurring from within distinct and separate starting points ignores the complexity of the situation on the ground. Considering the 'turn to partnership' through the lens of two distinct overarching discourses, or ways of acting, does however provide a way to illustrate the contrasts between various influences within international policy discussions of partnerships and PDPs and their related areas of health innovation and health research. This is particularly useful as often these debates around the justification of PPPs and PDPs (both within policy and academic communities) become simplified and debated – polarised even – from two distinct points (the business approach and the development approach). In this chapter I will bring together a number of the policy issues discussed in the previous chapters to explain the rise of PDPs such as IAVI and discuss their fit within the overarching (policy) discourses of the health, development and innovation sectors. In particular, I will discuss what could be called an overarching 'business approach' towards partnership and product development which both the previous chapters highlight often dominates discussion focusing attention in AIDS vaccine research on short-term goals and endpoints.

I will then discuss how these discourses interact with a number of operational level storylines, or ways of explaining, that both influence and are influenced by the discourses themselves. In particular, the impact of a dominant business orientated

discourse has created an equally dominant storyline at the operational level regarding the role of PDPs in combating market failure. This competes with another set of ethics related discourses at the operational level. This competition between storylines at the operational level of the IAVI partnership helps sustain an uneasy continued co-existence and interplay of both discourses. I will show how this is evidenced within the IAVI partnership in Kenya by its activities and people's attitudes to its activities taking place along a stylised organisational model continuum that has a strict pharmaceutical business approach at one end and an international development organisation approach at the other. As I will go on to discuss, often people's activities and ideas do not fit simply at one end or the other of the continuum. The reality is a much messier mix somewhere in the middle. An overview of the main aspects of the discourses, storylines and the organisational models is available in Figure 6.1. This figure provides a simplified illustration of the main aspects of each discourse, storyline and organisational model which I discuss in this chapter. As I have already highlighted, in reality two distinct approaches do not exist as activities create a complexity of practice that often removes the line between the two approaches particularly at the level of storylines and organisational models.

Discourse – the turn to partnership	Business and market approach	Development and participation approach
Storylines	Market failure in product development for neglected diseases	Ethics – research vs. care: Capacity building Development assistance Institutional linkages
Organisational models	Business orientated Outputs, goal orientation, targeted results, endpoints Short term	Development orientated Process, capacity building, sustainability, participation Long term

Figure 6.1 Discourses, storylines and organisational models

As a result, the final section of this chapter will discuss the implications of understanding the IAVI partnership in Kenya as the product of, and impacting, various discourses and storylines by highlighting the need to look more holistically at all influences on partnership activity for a full understanding to be gained. I discuss the importance of considering not only the meso organisational level activities of the IAVI partnership in Kenya but also the wider implicit structuring relationships and linkages working beyond it. I will argue that one way to achieve this is to consider the concept of 'assemblages' developed by Ong and Collier (2004). This provides a means of moving a further step away from value laden notions of partnership towards recognising the complexity at not only the partnership level but also within the wider arena that influences, and is influenced by, activities on the ground in Kenya by the IAVI partnership.

6.1 Dominant discourses

The notion of 'discourse' that I use in this chapter refers to a 'way of acting' based on both explanation and practice (Escobar, 1995; Foucault, 1972; Hajer, 1997). It is possible to acknowledge the existence of internationally prevalent overarching discourses within policy arenas (of health and international development) that emphasise a 'turn to partnership'. The rise of PDPs such as IAVI is part of this turn to partnership within the international health policy field. In both of the previous chapters the rise of partnerships for health product development has been a central focus but the ways of acting, the discourses, described have been very different. One discourse focuses on a more business orientated approach while another set of discourses focuses on an international development approach. I will now discuss the rise of these different discourses. I focus heavily on the business discourse because as the previous two chapters of this thesis highlight, its methods and approaches have come to dominate the way the IAVI partnership is often viewed and functions. I will provide an example of this in Section 6.4 below. I will discuss the competing nature of these discourses which is based on their relationship with various storylines that exist at an operational or partnership level in Section 6.3 below.

6.1.1 A business and market discourse

The rise of PDPs is part of a wider move towards the private sector in international health policy and an increasing 'commercialisation of healthcare' (Mackintosh and Koivusalo, 2005). This commercialisation is an example of one form of practicing partnership – one discourse – that has become dominant that relates to an emphasis being placed on business and market approaches. This thesis (see Chapter One) and Chapter Four in particular, have as a starting point, the rise of PDPs as a collaborative incentive mechanism for neglected disease product development in a situation of market failure. Partnership with the private sector or use of their methods is encouraged and is at the heart of PDPs, such as IAVI's, origins and methods. In this way Chapter Four has as its starting point a business oriented focus based on this discourse around commercialisation of healthcare and the role of the private sector.

International health and development philosophy changed from the late 1970s from focusing on public health for all towards the need for private sector efficiency. The international health policy discussion came to be defined in terms of the correct public/private mix (Bennett, McPake, et al., 1997) with a distinction being made between public health or disease control measures and (private) care provision (Mackintosh and Koivusalo, 2005; Unger, De Paepe, et al., 2006). The need for private sector involvement is couched in terms of efficiency and 'welfare optimality' often based on neoclassical economics, neoliberal political theory and more pragmatic decisions due to external and internal pressures (Bennett, McPake, et al., 1997). Of specific importance for the issue of vaccines for diseases such as HIV/AIDS has been the discussion of public health measures in relation to global public goods or goods that have non-rival and non-excludable characteristics, and cut across borders, leading to the potential for free-riding (Archibugi and Bazzarri, 2004; Dodd, Schieber, et al., 2007; Smith, Woodward, et al., 2004). Their apparent collective benefit (requiring collective action) and eradication nature reduces the incentive for the private sector to get involved in their production, as discussed in the introductory chapters.

Changing philosophies regarding the role of the private sector have also been influenced by globalisation and in particular the increasingly influence of international business corporations and international corporate alliances (Buse and Walt, 2002). There has been a globalisation of the market for health inputs (Mackintosh and Koivusalo, 2005). Industrialised countries and multi-national corporations are using legislation to ensure their vested interests and markets for drugs, vaccines and diagnostics are retained and strengthened (Hardon, 2001; Unger, De Paepe, et al., 2006). At the same time donors have increased their attention on new health product development and the role of private sector expertise in this area to assist in the creation and marketing of new health technologies (Hecht and Shah, 2006).

This is a very simplified account of the forces at work that explain the global heath policy architecture which has changed its focus from state to business and at the same time towards the promotion of technological innovation (Segaar, 2004). For many this complex situation can be summed up as resulting in a changing focus of international health policy "…from process to outcome; a shift in time frame from long to short; a drift in content from broad to narrow; a tendency in orientation from horizontal to vertical." (de Savigny, 2004: 3). As I have already made clear, such sharp distinctions between two competing 'visions' of health policy and development are not possible although they have value in making it easier to illustrate the complexity of the situation (similar to my reduction, in this chapter, of the 'mess' of ideas to two distinct overarching discourses).

As the above quote highlights, along with the rise in prominence of more business oriented activities and the rise of the private sector, there has been an increasing emphasis on short term gain, narrow definition of results and a focus on top-down decision-making. As I introduced in Chapter Four and discussed in more depth in Chapter Five this discourse results in an emphasis on end points, tangible results and a goal orientation to projects that can override focusing on broader issues of

sustainability, long-term gain and horizontal but complicated ways of decision-making.

While in some areas this narrowing of vision is changing with a renewed emphasis being placed on strengthening health systems by the UN, WHO and others (DFID, 2007; Unger, De Paepe, et al., 2006; WHO, 2000), global PPPs are seen to epitomise this reductionist strategy (Hardon and Blume, 2005; Walt and Buse, 2000; Walt and Lush, 2001) in particular the vertical top-down programming effect that they have.

Thus, PDPs and other forms of partnerships have been seen as developing out of a changing global discourse around the role of the state and business in providing solutions to poverty and disease. As discussed in Chapter Four, IAVI itself talks of its philosophy as being to bring private sector efficiency to an inefficient public sector. PDPs are seen as a means of promoting neglected disease product development in areas such as AIDS vaccine research, combating the market failure, by creating the right stimulus for private sector involvement. As Chapters Two and Four highlighted, IAVI was set up to increase scientific, financial and political activity in the area of AIDS vaccine development; to combat the market failure.

6.1.2 A development and participation discourse

Practising partnership has been increasingly promoted, as I outline in Chapter Two and Chapter Five, for a reason distinct to the prevailing business discourse focus on bringing in private sector efficiency. For many working within this discourse it provides a critical alternative to the market oriented discourse as made evident by the post-development critique of partnership outlined in Chapter Four. The underlying focus here is not the market but social justice. This alternative discourse present within policy circles emphasises international development concerns regarding sustainability, capacity building and participation. Partnerships, from this alternative perspective, are seen as a means of creating more inclusivity and participation within international development activities. As a result this discourse is more active through operational (micro) level storylines and therefore receives most discussion in the next section.

In recent years partnerships have been seen as a way to bring efficiency to the international development sector, focusing and simplifying aid in light of inefficiencies of the UN system (Dodd, Schieber, et al., 2007). An emphasis has been placed on building and strengthening capacity through productive and quality partnerships that are focused on developing local capabilities and skills. Local ownership and participation are stressed. At the same time the emphasis on results is less short-term and is focused instead on building quality processes that stand the test of time or as I quote Pickard in Chapter Four the creation of "long-term processes of social transformation."

It is in this way that IAVI aims to conduct its activities in developing countries such as Kenya. In trying to move away from being seen as 'Western' (Solnick, Ajayi, et al., 2003) IAVI has attempted to become more local with regional offices, CABs and networking with national level governments also outlined in Chapter Five. Chapter Five discusses partnerships from within the context of this other discourse. Focusing on the role and function of capacity building activities, Chapter Five discusses how partnership provides an opportunity for capacity building, sustainability and participation.

6.2 Competing Storylines

Alongside overarching discourses are operational level storylines. In this instance, these take place at the level of the IAVI partnership and its immediate surroundings. A storyline (c.f. Hajer, 1997; Hajer, n.d.) refers to 'ways of explaining' situations. Similar to the concept of rhetoric, metaphor or narrative, it is the idea of the creation of overarching notions that people identify with, contribute to, and use to bring others together towards a common understanding. I will highlight how the IAVI partnership and its activities are created and sustained by a number of competing storylines at the operational level.

6.2.1 The PDP mechanism storyline

One operational level storyline mirrors and, as I will discuss in the next Section, is influenced by the overarching business and market discourse around partnership. The storyline that dominated the creation of IAVI and its continued activities is, as highlighted in Chapter Two, an international (macro level) narrative of market failure and the rise of powerful global PDPs that work in ways similar to multi-national pharmaceutical companies, at the expense of 'the local' (national level institutions). This storyline is about how IAVI and other PDPs within the international health and development policy arena have been developed and shaped. The IAVI partnership was developed within, and has been shaped by, a predominately international health policy oriented (macro level) storyline that PDPs provide an innovative solution to solving market failures in access to medicines required by populations in developing countries. The idea is predicated in the assumption that once a product is made available the rest of the supply chain will fit in place. Although the need to consider access strategies more significantly is now on the agenda of many PDPs including IAVI (partly as a result of the development discourse around partnership) the international focus in the assessment of PDP activities, their usefulness and place occurs within an international dialogue around commercialisation of healthcare. This is an example of where the changing partnership and market rhetoric internationally – the dominant discourse – relates to IAVI's partnership format (as discussed in Chapter Four) and its activities outlined in Chapter Five. I will discuss this in more detail in Section 6.3.

6.2.2 A competing set of ethics related storylines

Previous chapters of this thesis have highlighted a number of other operational (micro) level storylines related to research ethics around the relationship between clinical research activities, healthcare provision and capacity building. This is despite the fact that most of the literature has largely neglected the impact of global PDPs on healthcare provision activities in developing countries and how they fit into a government's health research and innovation activities. Most of the literature takes as its operational starting point the PDP mechanism storyline – due to the dominance of the related overarching discourse – regarding a PDP's role in combating

international level market failure in the production of drugs, vaccines and diagnostics for neglected diseases. This is despite the fact that global PDPs such as IAVI have increasingly moved their clinical trial activities to developing countries such as Kenya, opened regional offices and have become involved in healthcare provision activities.

I found that on the ground in Kenya, partly as a result of but mainly reinforced by IAVI's activities, an alternative set of ethics related discourses were present in and around the clinical trial sites, the regional office in Kenya and local stakeholder partners. These revolved around a difficulty of emphasising healthcare provision activities with research activities and associated capacity building questions (as outlined in Chapter Five) within the constraints of existing research and ethical review guidelines developed within Kenya for AIDS vaccine clinical trials. In this section I will discuss how there has been a shift in the focus of national level health research activities towards the ethics and regulation of clinical trials and capacity building activities while health policy still emphasises treatment over research. I will argue that as such this may explain some of IAVI's approaches towards capacity building activities outlined in Chapter Five. These storylines are related to the earlier mentioned discourse around development and participation and which has also influenced the way this set of discourses has emerged and the emphasis given to capacity building. This linkage will be discussed in Section 6.3 below. I shall now briefly discuss the main aspect of this alternative set of storylines.

This set of alternative storylines revolves around the difficulty acknowledged with separating clinical trial research activities and healthcare activities. In my discussions and observations I made during my visits to Kenya I was struck by the attempts made to separate discussions and activity of clinical research and healthcare provision alongside the difficult reality of actually doing so. The starkest example of this was highlighted to me by the physical inability to split research and care activities despite attempts in some places to try to make them separate entities.

For example, when I visited KEMRI's site in Kilifi I was struck by the physical positioning of the research buildings with the district hospital. KEMRI's buildings were hidden from the main town by the brow of a hill and a high wall when you got to the top of the hill. The buildings themselves were new and shiny, in my field notes I write of it looking like a spaceship totally out of place with the bush scrub landscape and wet, pot-holed town beside it. Most interesting was the way it was connected physically with the district hospital; by a number of covered walkways all on a downward slope that led from various exits from the research buildings to different sections of the hospital. The walkways all took you through a gate (guarded) in the wall that separated the two sections of the site (research from care). Similarly, KAVI is located within the university buildings linked by a walkway to the main Kenyatta National Hospital building on a hill above the centre of Nairobi.

What is interesting about these descriptions is that they highlight the physical linkage between research and care activities which are so often seen as separate (Elston, 1997). Mary Elston talks about the physical separation between University College London and University College Hospital above ground but underground a number of tunnels join the two together. The Kangemi and Mtwapa sites involved in IAVI work are however different with research and care activities taking place in the same compounds, sometimes in the same buildings.

It is unsurprising perhaps that these two sites are the flagships for the design of future research sites by IAVI as they show the physical marrying of both activities. Unfortunately at none of the sites was there agreement that the perfect relationship between research and care existed and I was never able to find out what a 'perfect' balance of research and care should be in relation to these sites, although more recently there have been papers (Fitzgerald, Papea, et al., 2003; Fitzgerald and Wassuna, 2005; Weijer and LeBlanc, 2006) written and a session at the 2007 International AIDS Society conference that have tried to discuss this relationship more generically. IAVI itself has also started to address this issue (Berkley, 2003) and has published treatment and care guidelines on its website (www.iavi.org) in 2007.

In particular there appeared to be a variety of different attitudes and opinions dominating within the IAVI partnership regarding the degree to which an emphasis should be placed on care activities and their integration of research activities with existing local healthcare facilities. I will now outline the various arguments I heard with examples taken from one particular interview I held with an IAVI manager from the regional office in Nairobi.

Researchers struggled with the idea that capacity building was not part of their activities – they were there to do research only. My discussions with those at KEMRI in particular highlighted that this was not uncommon. Researchers talked about various colleagues who placed research and its results first and foremost in their activities. It is possible to find such comments outside of the AIDS vaccine field too. For example, in the New Scientist in 2006 in relation to malaria research a scientist is quoted as saying "Our clinics cannot replace a failing public health system… We're here to do research" (New Scientist, 2006)

A more pragmatic response I received was that care was only provided because they needed somewhere to do the research and this was inside a care facility. Examples of such facilities were the CCRC in Kilifi District Hospital and Kangemi health facility. As such, the care activities were seen by some I talked to as simply a 'by-product' of the research activities. So for example the IAVI manager saw care provision as a part of the research process; being seen as a necessary part of what doing research entails:

> "I would say that we, our primary mandate is scientific research. I believe that there are elements of health care provision that go along with that scientific research and to the degree that health care provision is necessitated by the scientific research we provide it. I think, it is something we are talking about a lot here and I think it's really important for the organisation to be very clear in terms of what their objectives are. I think especially when they work in research work in a resource-poor environment." [IAVI6; emphasis added]

In a similar tone, over half of all 62 people I spoke to (from not only within the research sites but also in the policy arena and IAVI itself) saw the need to offer referral pathways as being necessary on practical grounds. One reason given was

that it was felt that the facilities at the research sites did not have the resources, particularly the personnel needed to conduct healthcare provision activities. Related to this was the demand for care services from the local community who often saw the research sites as health care provision facilities.

More often than not however, I was given a moral argument regarding the need for IAVI research sites to become involved in care provision; sentiments such as the trial sites "can't not do it". The argument was that IAVI's research activities implied a duty of care because some IAVI studies involve HIV positive cohorts. This was reinforced by an attitude that positive changes were being made with vaccine literacy work around the trial sites towards attitudes, knowledge and practices towards HIV/AIDS. This was linked to an IAVI led argument that facilitating support of local healthcare provision and referrals should enhance community awareness and understanding regarding the AIDS vaccine research work. In particular, IAVI stressed the development of integrated approaches that moved away from the trial sites providing treatment and care directly to HIV positive trial participants and screen outs. The focus was on working together to build up local healthcare facilities to provide VCT, ARVs and general healthcare services. Thus the IAVI manager highlighted that there was a personal imperative to the issue – a moral stance needed to be taken such that you "can't not do it":

> "It's good for the community, it's the right thing to do. But is it the right thing for IAVI to do and where do you put the boundaries on it? Myself, informed by the organisation's overall objectives, the way I define it is that IAVI is bound to provide health care services for individuals who participate in our trials. I think that in terms of individuals who come forward to participate in trials who screen out if they're HIV tested, we're bound to provide either health care or a fast referral pathway that is beyond just a blank sheet of paper that we don't know where to go with it or whether or not they use it. We need to be sure that there are other referral pathways that people are using. I think that's sort of, the first is absolute. The second is one of the most important, the screen outs, in terms of IAVI's objectives, are the second, in order of importance. People always say people deserve health care because they're people, not because they participate in trials. And that's exactly right." [IAVI6; emphasis added]

However, a number of actors from a variety of different perspectives (clinical research, IAVI and government) clarified their positions by acknowledging that at some point a distinction had to be made between what was necessary care support for

research activities and what should be left to the healthcare domain more generally. This is also reflected in IAVI research site policy whereby clinical care is provided to trial participants and not to their dependents and also relates to decisions within IAVI to work with local healthcare providers to improve care provision more generally to allow for robust referral pathways that reduce the strain on IAVI clinical research sites to become equivalent care provision centres. This was usually couched in terms of resource allocation as per the comments of the IAVI manager I spoke to:

> "But for an organisation with limited funding and a research mandate, again, where do you put those boundaries? I mean, KAVI is in Nairobi so where are the boundaries? Screen outs, family of volunteers and then the third is the rest of that overall community. So in a place like Kangemi where there are very key services provided in site, the primary service provider is the Nairobi City Council. IAVI's objectives are to provide services for our volunteers, but we have a limited amount of staff at those trial sites and in such a resource poor setting and such a poor population… Boy, out there, there are huge… and people are not well and they have a lot of needs. They would swamp the research if you include the screen outs in terms of the number of individuals that are providing… So what IAVI's objectives are is to build up the capacity of the Nairobi City Council to be able to accommodate those you screen out. I mean, because they are HIV positive or because they have other health care issues." [IAVI6; emphasis added]

Thus my discussions and observations during my fieldwork presented me with a variety of different attitudes towards the ethics of clinical research that have created an alternative set of storylines about what is important for the day-to-day operational activities of the partnership. These do not place an emphasis on combating market failure or improving efficiency to explain the need for partnership. Instead, the emphasis is on the processes that are required to ensure successful vaccine development related to the needs of all those involved. The discussion above has highlighted how this touches upon the need to build local capacity and strengthen health related infrastructure in developing countries. It also highlights the importance of good process and the value of strong organisational and networking structures to ensure the provision of healthcare treatment during clinical research activities.

6.3 Fit between discourses and storylines

The relationship between these two macro level discourses and the various operational micro level storylines is not simply a discussion of the macro affecting the micro. The reality is more complex with influencing and re-influencing occurring on both sides. This mirrors a wider issue about the relationship between macro and micro forces in social theory. The relationship between discourses and storylines is impacted by the perspective taken and the actors involved. I will now discuss each of these issues in more depth.

6.3.1 The relationship between discourses and storylines

I found a disconnect between the way the IAVI partnership is understood and considered within (international) health policy circles and how it is understood on the ground in Kenya. While one focuses at the macro level on the role of the IAVI partnership in combating a market failure by incentivising product development and what is needed to reach this goal, the other perspective focuses on the operational activities of the partnership and building longer term capabilities at a micro level.

An alternative 'reality', as has been outlined in previous chapters as well, is that the IAVI partnership is not a single homogenous entity and understanding the reasoning behind the IAVI partnership, how it works and is promoted cannot simply be put forward by a single policy discourse. There are multiple discourses or ways of acting, of practice, taking place. In particular, studying how IAVI as a partnership works on the ground in Kenya has highlighted to me how complex the interplay between dominant storylines and discourses are but also how these discourses themselves then impact on, but are also impacted by, activities that take place under the banner of a particular storyline resulting in the reconstruction of discourse.

Discourses are not only defined by dominant storylines but are also responsible, in turn, for maintaining dominant storylines. My use of the term discourse differs from

that of Hajer to whom the term 'storylines' is often attributed to. For Hajer, discourses are created through storylines (Ockwell and Rydin, 2006) around discourse coalitions where actors coalesce and share a set of storylines over time (Hajer, n.d.). My use of the term discourse includes elements of what Diane Vaughan terms 'institutional logics'. As such it sees storylines not only creating discourses but that discourses also in turn influence how storylines play out. Based on DiMaggio (1997) the concept refers, for Vaughan, to globally dominant organising beliefs and practice that originate "in the environment (professions; industries; American society)" but which in turn are affected by "practical activity" and are "reproduced in the course of that activity." (Vaughan, 2002: 26). My research of IAVI highlights how a dominant discourse does not simply produce a single dominant macro level storyline because there are other sets of micro level storylines that also determine how the IAVI partnership is understood and supported.

6.3.2 Part of a wider micro-macro debate

The argument I make mirrors an acknowledgement of this complexity within social theory. In discussing the relationship between discourse and storylines I am raising the issue of the relationship between macro level issues and micro level activity. The overarching discourses I have discussed developed within a predominantly international or global policy setting in the sense that they are discussed across territorial and spatial boundaries between actors who are involved in finding solutions to the world's health problems or are involved in promoting innovation and economic development in developing countries. The storylines however refer to ways of explaining and enrolling support for partnership activities at an operational or more micro level.

Questions about how the macro environment affects and determines what happens at the meso (organisational) and micro (individual) level have been asked by those from within science studies in terms of the interrelatedness between these different levels and, in particular, the relationship between the micro-social and the macro-social (Knorr-Certina and Cicourel, 1981; Latour, 2005). In particular, they ask does one

influence the other? Does it occur as a result of a chain of events, up from the micro-level or down from the macro-level?

On the one hand, it is possible to argue – as much of the post-development literature does (Crewe and Harrison, 1998; Fagan, 1999; Pieterse, 2001) – that international development such as that exemplified by the IAVI partnership in Kenya, is an example of the macro influencing the micro or of what they would term 'top-down' development. As I have outlined in previous chapters of this thesis, there is a dominance of an international level notion of why partnership is required and the role of partnerships – particularly partnerships developed and managed from countries in the developed world – to incentivise vaccine development and 'develop' the capacity of developing countries such as Kenya in the area of vaccine clinical research. However, I have also shown how in the case of the IAVI partnership in Kenya there are other storylines that provide an alternative outlook. It is for this reason that my analysis of the relationship between discourse and storylines is a two way relationship.

Although these alternative storylines and its related discourse often do not receive as much focus at an international level – discussions around PDPs and health research have been less about ethics, rights and capacity building and more about combating the market failure – they appear to be particularly relevant for understanding the activities in Kenya of the IAVI partnership. This is not to say that there is not an alternative, even dominant, storyline at the operational level in Kenya or that it is not influenced by, reflects and reinforces what I have termed a business discourse. It does. However, there is at least one other discourse and set of storylines also in evidence that vie for attention alongside these more dominant alternatives.

Escobar calls for "the investigation of alternative representations and practices in concrete local settings" (Escobar, 1995: 19) to examine realities and alternatives to post-colonial top-down development. This is what my PhD thesis has done by looking at the IAVI partnership on the ground in Kenya. By focusing on the process of partnership and capacity building through an in-depth institutional level analysis, I

have been able to conduct "a deeper analysis of the way in which actors operate to stabilize interpretations and produce meaning, social networks, and development success at every level" (Mosse and Lewis, 2005: 15) by getting to grips with the black box of process often ignored in consideration of not only international development (Mosse and Lewis, 2005) but also of innovation activities (Weber, 2002). But in so doing, my analysis has not highlighted a 'reality' in terms of post-colonial top-down development but as a complex and nuanced interconnection of forces, actors and relationships.

My investigation of one local setting provides for a nuanced explanation of the IAVI partnership and as such one that is less easily explained by an overarching discourse and operational storyline that PDPs are the result of a market failure in the area of product development for neglected diseases. It is not simply a matter of this dominant storyline affecting how activities play out on the ground. There are multiple actors and more 'agency' involved by these different actors as a result of their interactions with each other and with activities, processes and objects. As a consequence, there are a number of other storylines that are worth noting which dominate at different 'levels' of analysis and which impact and influence each other. Alongside the main storyline around the market failure in product development are storylines around good organisational processes (i.e. the need to include healthcare provision in clinical research settings) and about capacity building and the role of international development partnerships. The existence of these has also been highlighted in previous chapters of this thesis.

The evidence of alternative storylines and discourses fits with the critiques of post-development theory that emphasise the difficulty of a black and white or binary perspective such as that put across most contentiously by the post-development theorist, Arturo Escobar. In his 1995 polemic book *Encountering Development: The Making and Unmaking of the Third World*, Escobar argues that development activities can be seen as a top-down process whereby existing inequalities are reinforced and perpetuated so that developing countries are dominated by Western countries of the developed world. This argument is also made, somewhat less

contentiously, by two other texts closely associated with the post-development approach: *The Development Dictionary* edited by Wolfgang Sachs (1992) and *The Post-Development Reader* (1997) compiled by Majid Rahnema with Victoria Bawtree.

However, as argued by the critiques of post-development theory (c.f. Gardner and Lewis, 2000; Kiely, 1999; Pieterse, 2001; Storey, 2000), the IAVI partnership in Kenya highlights the difficulty of asserting a binary or bi-polar distinction of top-down development. In discussing the problems of post-development theory Pieterse writes:

> "'Post-development' is misconceived because it attributes to 'development' a single and narrow meaning, a consistency which does not match either theory or policy, and thus replicates the rhetoric of developmentalism, rather than penetrating and exposing its polysemic realities." (Pieterse, 2001: 111)

A reality of international development activity more generally, and the IAVI partnership in Kenya more specifically, is much more complexity, highlighting a variety of different storylines and discourses vying for attention creating a number of different forms of power and politics between a multiplicity of actors. The critics of post-development theory talk about the need to consider the 'hybridity' of development research (Kiely, 1999; Müller, 2006), the existence of 'multiple narratives' (Gardner and Lewis, 2000), the multifaceted nature of participation (Peters, 2000) and an analysis that emphasises 'holism' and 'synthesis' to work towards 'reflexive development' (Pieterse, 2001). In studying a local setting – the IAVI partnership in Kenya – I have examined the hybridity of development activities, highlighted the existence of multiple narratives and I have discussed the need for a more holistic approach.

6.3.3 Depends on perspective and actors

My research has highlighted how the complexity of different discourses and storylines creates a situation whereby it is no longer possible to simply say that the way the IAVI partnership works on the ground in Kenya is due to its exhibiting the shift towards vertical top-down programming in the light of the turn towards

neoliberal thinking in the international health and development arena and the consequential shift towards a narrowing of emphasis on outcomes and short time frames. There is no one single dominant discourse or storyline but many that vie for attention and change depending on the position of an actor and the subject from which analysis starts.

Understanding the activities of the IAVI partnership at the country level is not clear cut. The IAVI partnership in Kenya reflects the perspective from which the partnership is considered and the actors looked at; the partnership reflects who has influence that impacts which discourses and storylines become dominant and where and when they are discussed. It is not simply an issue of PDPs being used as a way to ward off a market failure and its requirements in terms of the incentives and governance structures this requires as argued by much of the PDP literature. It is not simply an issue of the influence of one dominant storyline but of a number of different storylines being acted out. It is important to understand the transformations within different discourses and storylines that create different impacts at the operational level.

It is also possible to see in Chapter Five the role of influencing and re-influencing between the micro and macro levels. Re-influencing occurs as a result of cyclical feedback which means discourses do not simply influence storylines but create a situation whereby the macro environment can be built out of micro level activity. An example of this is the increasing influence being placed on capacity building by IAVI internationally as a result of the way it has had to engage in capacity building on the ground in countries such as Kenya. This may be the result of the gathering pace of international development perspectives on capacity building or as a response to the critiques and to justify their clinical trials in developing countries. Similarly, it may be possible to argue that one of the reasons for the continued emphasis placed on PDPs is their ability to demonstrate their success. IAVI has conducted several trials each one leading to a furthering of knowledge regarding what is required to develop an effective vaccine. Although IAVI has yet to develop a vaccine, other PDPs, such as the Drugs for Neglected Diseases Initiative (DNDi) and Medicines for Malaria

Venture (MMV), have developed and marketed products showing that the formula does work. Each of these successes influences the dominance of different institutional logics within the wider environment.

However, the rise of new incentive mechanisms in the international policy arena such as Advance Market Commitments, whereby governments contribute to a fund that guarantees the purchase of new neglected disease health products, which do not require a PDP or even a PPP for their use are also examples of how re-influencing can take place. This is not only as a result of the connections around the PDPs but due to external policy shifts. This therefore again complicates the macro-to-micro or micro-to-macro linear and binary process of policy and activity creation.

It is also important to mention that while much of the emphasis of this chapter has been on actors and activities within IAVI (the focus of the thesis being IAVI) this does not exclude – as the above example shows – different actors external to IAVI or on the periphery of the IAVI partnership to be instrumental in how, and which, discourses and storylines are dominant. The Government of Kenya is, for example, an important actor that has the potential to influence these discourses. Internationally the Government of Kenya has at times become an important actor. For example, Kenya together with Brazil put together a proposal to the WHO World Health Assembly for an international R&D Treaty for neglected disease product development in 2005. However, the Government of Kenya has not shown – on the basis of my research – as strong a stance in the promotion of AIDS vaccine research. This may be due, as I discuss in my methodology chapter, to the way I have told the story (focusing too heavily on IAVI) but it may also be a consequence of the type of partnership mechanism (parental) that has developed within Kenya around IAVI's vaccine development research and the partnership dynamics that have resulted.

Despite the Kenyan government taking a strong lead internationally in the area of health research and the promotion of R&D, this same lead did not appear to me to have taken place internally within Kenya. I have already introduced in Chapter Four the notion within Kenyan policy circles of a linear top-down governance structure

around AIDS vaccine research and the general dominance of IAVI within this structure. Further to this, in my discussions with those within Kenya's policy circles, an emphasis was placed (to varying degrees) on the financial power that IAVI had, thus reiterating to me the idea of the Kenyan IAVI partnership taking a parental form mirroring traditional donor-recipient relations of the past and increasingly even of the present.[27] It was not surprising to me therefore when one government official talked of the importance of IAVI's support to KAVI because the government did not have the finances to support health research over the long term and in the same in-depth manner as IAVI could. This obviously has implications for the sustainability of a research centre such as KAVI where funding of the centre is provided in its totality by IAVI. Although it is important to point out that all the senior staff at KAVI were confident that they could survive should IAVI funds cease. Yet such a precarious situation is reiterated and reinforced by figures on health research spending. These highlight the difficulties for countries such as Kenya to spend the recommended 2% of national health expenditure on health research activities when only at present three low and middle income countries all outside Africa meet this target (de Francisco and Matlin, 2006).

This one 'take' or potential explanation for the power and influence of IAVI within the partnership activities and more generally in the Kenyan health policy arena is strangely also reinforced by the rise of clinical trials in developing countries and the focus on standardisation referred to in Chapter Five. This focus at the level of the clinical trial field sites creates a situation where clinical research activities – through clinical practice guidelines and protocols – become no different regardless of their setting; the way a trial takes place in Kenya is the same as it would in Thailand, Poland or the USA (Timmermans, 2005). In discussing clinical trial activities it becomes too easy in this instance to consider activities without taking into account issues of the wider context. This one way of doing things appears to be that which is promoted and pushed by IAVI with its endpoint focus and which permeates through into policy discussions.

[27] For a discussion of global health governance see the work of Kelley Lee or Ted Schrecker and colleagues (c.f. Kirton, Schrecker, et al., 2007; Lee, 2003).

However, IAVI was not always dominant as I shall go on to discuss later in this chapter. The Kenyan government does have a 'voice' and a say in how clinical trials take place and the role of health research in Kenya more generally. I will shortly discuss how the Government of Kenya is trying to strengthen its health system and provide better HIV/AIDS care and treatment. This is an important backdrop discussion within which AIDS vaccine trials in Kenya take place. However, there are also competing demands within the Kenyan Government on the emphasis between research activities and the immediate healthcare provision requirements (treatment and care for AIDS patients, for example). All of those I spoke to within government (both at national and district levels) told me that treatment and care dominated the national health policy agenda at the expense of research activities and more specifically vaccine research activities. Again, this was reinforced by my government based interviewees making statements about the lack of financial support granted to research activities and their related government departments as opposed to healthcare provision activities. One NGO based interviewee went as far as to say that this was due ultimately to the short term perspective of the politicians who make budgetary decisions (concerned with their own political survival) rather than considering the long term requirements for financial and political support of an AIDS vaccine. Thus power is held by Kenyan politicians that can affect the ability of IAVI and its research partners to meet their vaccine development goals. Should politicians – as I was told they do – focus heavily on HIV/AIDS treatment and care over prevention and research activities, this will impact the ability of clinical trials to successfully take place.

This is also set against a further storyline of competing government ministries (the National Council for Science and Technology, now a Ministry in its own right, and the Ministry of Health) for control of health research activities in the Kenya. The historical development of KEMRI and its location at different times within each of these ministries is one such example of this power contest.

The overall policy situation is therefore more complex than simply a top-down parental partnership notion would suggest depending on who one talks to and when.

There is in fact a complexity of views, potential 'takes' to the story or ways the situation can be explained depending on the starting point from which the story is taken.

6.4 Evidenced along a continuum

The interplay between the macro level discourses and these micro level storylines and the complexity produced evidenced within the IAVI partnership in Kenya by its activities, and people's attitudes to its activities, can be more easily visualised and understood when seen to take place along a stylised organisational model continuum. At one end of the continuum can be placed the pure business model approach following similar lines to a pharmaceutical company with an emphasis on speed and efficiency while at the other end of the continuum one would find the international development model emphasising capacity building, participation and sustainability objectives. People's attitudes and the place they have along the continuum are the consequence of differing and competing storylines and discourses that are used to justify, explain and promote product development for neglected diseases, international development partnerships and clinical research in developing countries.

The result is a conflict of attitudes and ideas – of 'cultures'[28] – along the continuum between those who work within IAVI which spills over into the way the IAVI partnership as a whole is structured and operates. There is an overall focus on speed and efficiency and short term goal attainment due to the emphasis placed on product development activities; on a business 'culture' of ensuring a strong and efficient product development pipeline and the completion of projects in a timely manner. This can be separated from a 'culture' from within the international development camp that emphasises more long term efforts, sustainability and capacity building. This latter culture has been strengthened by the necessity of working in, and the needs of, developing countries such as Kenya where the capacity to conduct clinical trials was not strong. As I shall outline in this section, the position a person or

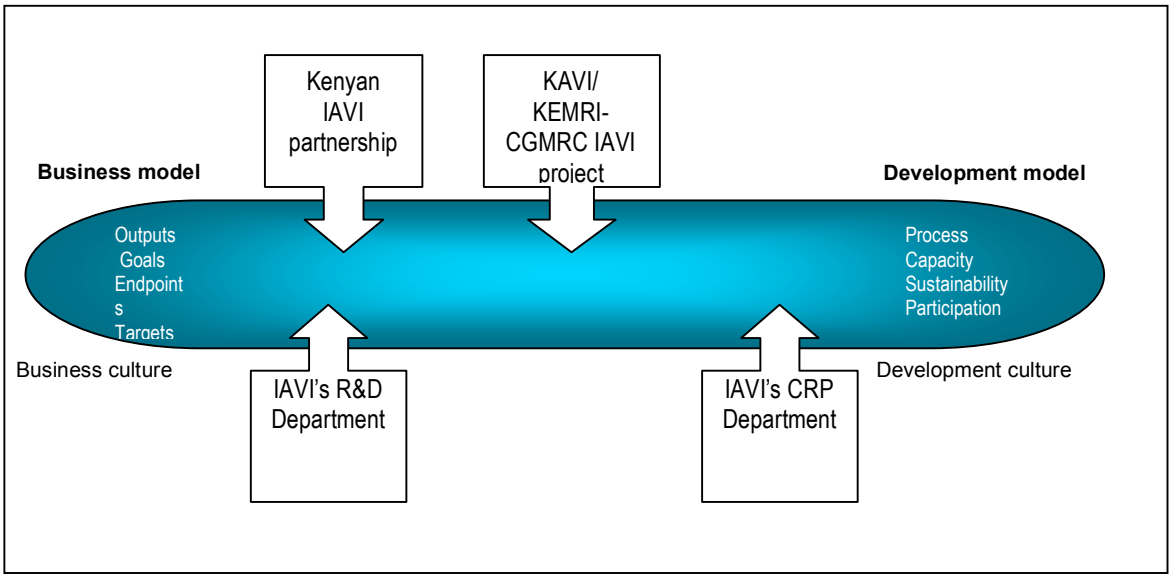
[28] Being aware of the contested nature of this concept, I use this term very loosely.

activity has along the continuum is often the result of a complex mix of discourses, storylines and organisational models and as such rarely fits into the extremes of either end of the continuum.

These cultures have developed out of and contribute to the storylines and discourses that vie for attention. These are important for determining the organisational model type that the IAVI partnership as a whole in Kenya and its various different actors within it use. Many of the discussions I held with people during my fieldwork provided examples of cultures that fit somewhere in between the two ends of the continuum. However, taken together the IAVI partnership as a whole in Kenya, in terms of its operational activities, appears to be placed towards the business end of the continuum although individual actors and institutions can be found at varying places along it.

Figure 6.2 provides an overview of this continuum and some examples of where the IAVI partnership in Kenya and various actors can be seen to fall along it. The previous chapters have highlighted how the research organisations KEMRI-CGMRC and KAVI juggle the divide between focusing on research and care in conducting clinical trial research for IAVI. This places them in the middle of the continuum, although individual staff members' attitudes fall in a variety of places along the continuum. For example, the nurse counsellors I spoke to were often overtly concerned and occupied with issues of volunteer healthcare on a day-to-day basis fitting with traditional international development organisation concerns. From another perspective, a number of the PIs and certain project coordinators were more concerned with undertaking research in a more goal oriented manner that fits more with the business model approach. To give a more in-depth overview of how the cultures fit across the continuum I shall address this with respect to the competing cultures I found within IAVI, the not-for-profit.

Figure 6.2 Kenyan IAVI partnership along an organisational model continuum



6.4.1 Different cultures and organisational models within IAVI

In the last chapter I outlined details of discussions I had with a PI which I used to highlight the complex nature of the work of IAVI and its partners on the ground in Kenya due to the competing demands of staff expectations, IAVI's goal and the demands of the work activities themselves. The result I argued is that IAVI has ended up 'doing development without doing development' (Chataway, 2005), engaging in capacity building activities because it had to rather than as an overt goal or output of partnership activities. Instead IAVI, the not-for-profit, is driven by a goal of ensuring development of an effective AIDS vaccine and uses a virtual business model approach (outlined in the introductory chapters) revolving around its R&D department to achieve this. Yet there has been increasing recognition of the need to conduct capacity building activities and, as I outlined in Chapter One, IAVI developed a specific CRP department in 2003 to "create a stronger, structured, and responsive presence while fostering broad-based advocacy and ensuring high quality to meet global standards of research" (IAVI, 2006: 12) and at the same time opened a regional office in Nairobi to facilitate these activities to create a local presence and trust amongst local partners.

Despite a sense that discussion is required and occurs between the R&D and CRP sections of IAVI in order for work to take place effectively within IAVI's regional office, a disjuncture between the priorities and underlying focus of each section was acknowledged by those within IAVI. The sense that IAVI staff are divided into two areas of focus is acknowledged by staff within IAVI as exemplified by this quote:

> "I always think of IAVI as having two arms, the research arm and then sort of the advocacy arm, and the advocacy arm includes a lot of the community outreach side of it… We have IAVI research staff that sit in this office and they are the primary contact people in terms of oversight and support for all the research activities that take place at both the clinical trial sites and the feasibility sites. The CRP programme staff, including myself, would be the primary point people for again some of those supportive activities. There is a bit of a grey area there in terms of what is classified as research and what is classified as CRP, anything there would be, anything having to do with recruitment would fall under the purview of research… If it was something related to counselling training, training counsellors and surrounding, how do you counsel HIV positive individuals who are enrolling in Protocol C then they would talk to CRP" [IAVI6; emphasis added]

However, there is also recognition that on the ground it was difficult to separate these activities as exemplified by this quote:

> "We have in terms of organisational structure and all that, I think, it's the management structure is quite… in terms of performance, the fast pace of performance, looking at what are the objectives and what are the outcomes its impressive – the corporate culture. There's quite a gap between medical affairs and CRP activities. But from the last meeting, I'm really happy to see that we are really working closely together. And which is, from my own perspective, at the regional level and in this office, you can't see the difference because they always work together with people on the ground but probably at the New York level then you can start feeling that things are purely medical affairs or purely CRP. But for me having worked here for six months at least in this office I've not seen any difference. I work closely with the medical people. It's really a team work effort on the ground." [IAVI3; emphasis added]

Finally, I am including a long quote below from one other IAVI staff member. The value of this long quote is that it gives a sense of the complexity of the situation highlighting the way people at IAVI have to negotiate their identities and the reasons for these different identities including different career trajectories:

> "We have these two personalities which have yet to merge completely. One personality is this high level R&D set up. That is all the finances, the

> structures, the personnel are all geared towards a given research of a vaccine. So that is one personality. The other personality is the emerging Country and Regional Program, which basically wants IAVI to resemble other international organisations like FHI [Family Health International], like Population Council, which have one presence in a region of countries.
> And there are reasons why this transition is taking time. One of the reasons is that people are coming in from different backgrounds. And this multi-disciplinary nature of our team is important. We have people coming in from the private sector for whom, you know efficiency is very focused on delivering results, for a given mission, for a given objective. So things like capacity building and doing… you know, like training people for their own sake and remaining behind rather than training people for a given activity doesn't quite make sense for them.
> For the group of people who come in from the private sector, it's not their business to go on developing capacity, it's their business to do specific activities and make an achievement. So our indicators are all focused around that objective. And at the other end of the extreme we have people coming from development agencies who have these – let me call them five words – one is 'sustainability', two is 'integration', three is 'capacity building', four is 'M&E [Monitoring and Evaluation] and accountability', they go together. I think those are… maybe there are four words…" [IAVI1; emphasis added]

As exemplified by this last quote, the disjuncture between the different sections of IAVI are due in part to the different personalities that are involved related to the different work focus and underlying philosophy that each section has. First and foremost, as explained in the introductory chapters, IAVI is described by its founder as a virtual pharmaceutical company. As such its activities are similar to that of any multi-national pharmaceutical company which are increasingly involved in networking and the management of networks with different groups at different stages of a candidate product's development (Powell and Gordal, 2005). Yet at the same time, it grew out of an increasingly international awareness of the role partnerships can play in delivering international assistance and is funded to a very large extent by money from international development oriented philanthropy organisations such as the Bill and Melinda Gates Foundation, a major IAVI funder. These organisations emphasise giving back and providing opportunities to ensure the ending of disease, hunger and poverty. The result is a complex set of identities and attitudes along a continuum making it difficult to define the IAVI partnership activities as using any one organisational model.

6.5 The reality is complexity

This analysis of the various discourses, storylines and the fit between them within the IAVI partnership in Kenya along an organisational model continuum outlines the degree of complexity that the types of collaboration and capacity building that takes place and has been outlined in the previous two chapters of this thesis. It is important to understand this underlying context within which the partnership is visualised (and in fact my own analysis in previous chapters has taken place). The IAVI partnership in Kenya is a hybrid entity as a result of competing cultures vying for attention and influence based on the interaction between different overarching macro level discourses and operational micro level storylines. How these cultures are taken up and transformed is specific to time and place along an organisational continuum between an overt pharmaceutical business model approach and an international development organisation approach. As such, the IAVI partnership on the ground in Kenya is not a simple example of a vertical top-down programme coming out of the wider policy move towards neoliberal and neoclassical economic arguments couched in terms of an market failure and the role of the private sector. A dominant culture may be the business model but this competes with a culture emphasising capacity building and sustainability. The result is a complex interplay of different cultures, organisational models, storylines and discourses.

One way of viewing IAVI is that the business model of IAVI is the result of an overarching discourse and related operational level storyline that focuses on bringing private sector efficiency to the public sector. This 'reality' appears to dominate the way IAVI conducts its activities internationally but also ultimately, how it works on the ground in Kenya, influencing who it partners with and how it partners with them. However, it is not a clear cut process as there is a necessity for the IAVI partnership to be more inclusive and networked as per the organisation's international development origins and background. As such, IAVI's regional office in Nairobi places attention on the need to focus on strengthening processes, networking and local ownership. The result is a wish within IAVI to be more inclusive, horizontal and focus on process over outcomes. Yet these constantly come up against the

business model emphasising speed, efficiency and goal-attainment. IAVI is made up of competing tensions and competing mediating groups, the negotiation between which has resulted in a complex interplay of both vertical programming and more horizontal (and inclusive) programming activities.

Buse and Walt (2002) argue that global PPPs were part of a shift towards the networked society and a move from vertical integration to horizontal integration. However, although the concept of a networked society and partnership definitions themselves suggest a level playing field with equal power and opportunity this is not often the case (see Chapter Four). As such, Walt and Lush (2001) highlight the difficulty of global PPPs to get drugs where they are needed. This is because the agenda is dominated by a narrow approach focusing on single issue diseases particularly three specific diseases (AIDS, TB and malaria). However, more importantly, it is because of the country level costs of getting involved in a PPP's activities which introduce new vertical systems into fragile health systems.

IAVI is one such product development PPP that can be seen as a single issue based partnership that is constantly fighting between working as an independent (vertical) silo or in a more integrated fashion. My discussions and observations highlighted that the work of the IAVI partnership in Kenya focuses attention on HIV/AIDS research, and perhaps even one specific section of such research (AIDS vaccine research), at the expense of other diseases and issues with implications on staff, equipment and resource allocations. At the same time, IAVI has struggled with discussions regarding the degree to which it will engage in care provision for HIV/AIDS positive trial participants, their families and the wider communities around the trial sites.

The implications this has on existing health and research systems was not lost on those who worked with IAVI when I talked to them. One IAVI member of staff I spoke to told me that there was a worry that by putting people to work on AIDS vaccine trials they might be taking expertise away from other areas creating some kind of shift in expertise. He felt that one way of avoiding this was to work with

others to build a pool of future expertise by working to strengthen the mainstream education system. In terms of the implications of getting involved in care activities, another member of IAVI staff told me:

> "Yes, we find we have to do it [work in parallel to the public health system] and we are guilty about it. We do it with guilt because the progressive thinking among other donor agencies is, 'let us integrate everything'. But even those test kits [for HIV] are supposed to be delivered by government but are bought by other donors. So, we feel guilty about it but we do it because we have to. We have indicators, our own targets to meet…" [IAVI1l]

He went on to talk to me about the impact IAVI was having on the policy agenda in the country and the focus being placed on vaccine research. His discussion with me highlighted the fact that IAVI partnership activities had (as outlined in Chapter Five) improved the national policy enabling environment by bringing in more actors and increasing dialogue and regulation around AIDS vaccine research activities. However, he went on to say that the issue of who was in control of this process was less clear. These issues can be illustrated with this quote from our discussion:

> "Yes, first of all, there is some negative reaction we need to deal with because we have overdone it [the creation of a national policy enabling environment]. And this reaction is coming from the other partners who are saying that we are making people believe vaccines are the only things to think about. So that kind of envy we have to deal with it. We want people to join in rather than say that this IAVI approach is really over doing it and how can you go and take over the national regulatory authorities to support them to do all these things, you know. This is not sustainable and your agency is very small and why are you going so fast? So that is the recorded backlash. But apart from that it can set a precedent that I think can be used in the future. That working under an umbrella such as the AAVP [African AIDS Vaccine Program] which is neutral we can, as a given stakeholder, we can influence government to improve regulatory policies or disseminate regulatory policies that are supposed to regulate us. You know, our approach can be used in other situations." [IAVI1l]

This raises issues of power and politics in relation to how IAVI interacts with other groups on the ground in Kenya to conduct its activities around the trial sites and create a wider AIDS vaccine research (policy) network collaboration. IAVI wants to, and has to (in order for its activities to take place), ensure that the partnership and its wider collaboration in Kenya are more horizontal than vertical in make up, that it is more inclusive. However, as the quote above highlights, the partnership activities

and those of the wider collaboration are dominated by IAVI's assistance which takes the discussion back to the issue of seeing the IAVI partnership as a form of parental partnership discussed in Chapter Four.

In particular, it highlights how IAVI can be seen to be playing a parental role not only in terms of facilitating AIDS vaccine research in Kenya but also in the creation of a wider national AIDS vaccine research network around the sub-committee's activities. This is related to IAVI's regional office's activities being focused on issues similar to those of a regular international development organisation but that its role is to play a supportive role to the business activities. The result of which in Kenya has been IAVI's engagement with policy activities to build a regulatory framework for AIDS vaccine research activities, including the setting up of a multi-actor committee and the development of national AIDS vaccine research guidelines.

As already mentioned, in 2003 IAVI opened a regional office in Nairobi to create a local presence and trust among local partners as part of the move to conduct vaccine preparedness activities by the CRP. In this office they have a Senior Policy Advisor. One of her roles is, as she described it, "to be a conduit between the researchers and the policy levels. (The community is dealt with by others in the regional office), at the MoH [Ministry of Health] and parliaments" [IAVI5]. In particular she has been responsible for lobbying the government, particularly the Ministry of Health, for the setting up of a national HIV vaccine sub-committee under the Director of Medical Services. The sub-committee is composed of all national stakeholders involved in or affected by AIDS vaccine research and meets once a month. The first activity of the committee was the development of the 'Kenyan National Guidelines for Research and Development of HIV/AIDS Vaccines' published in March 2005 by the Ministry of Health. This document's development and publishing was financially and logistically supported by IAVI. The document outlines the research approval process for any AIDS vaccine research activities including the scientific and ethical review process as well as the correct research conduct and procedures regarding site checklists, monitoring, informed consent, laboratory requirements etc. Around the same time the National Council for Science and Technology developed a national

guideline document relating to ethical conduct of research activities, 'Guidelines for ethical conduct of biomedical research involving human subjects in Kenya' (National Council for Science and Technology, 2004).

In line with these guidelines, the sub-committee's main activity is to review any AIDS vaccine research proposals before they go on for scientific and ethical review. I was informed that an IAVI representative often steps in as chair of the meetings, that the sub-committee was made up for the most part by those with connections to IAVI's own research activities and that without IAVI's financial support the sub-committee would not be active. Despite these feelings regarding the dominance of IAVI within the AIDS vaccine research arena in Kenya, there was general agreement amongst those I spoke to involved in Kenyan AIDS vaccine research that the work of the sub-committee and particularly the guidelines developed were an important step forward, not least ensuring that there was a specific regulatory pathway for research proposals to follow aiding the speedy progress of research activities. There was also acknowledgement that IAVI's activities in the area of AIDS vaccine research, including its policy facilitation, were needed as the Government of Kenya lacked important resources.

Again such sentiments and examples brings us back to the idea, outlined in Chapter Four, of IAVI playing a parental role not only in terms of facilitating AIDS vaccine research in Kenya but also in the creation of a wider national AIDS vaccine research partnership or network around the sub-committee's activities. This is related to IAVI's regional office's activities being focused on issues similar to those of a regular international development organisation but that its role is to be supportive to the business activities. IAVI's regional office activities, while like an international development organisation, are still dominated by the business approach. The international development type activities are undertaken because they facilitate IAVI's own research agenda. Ensuring a strong policy environment ensures its own research protocols are sent through the system faster. The business model of the virtual pharmaceutical company approach carries through to the way IAVI's regional

office activities are conducted and the emphasis placed on various enabling environment and vaccine literacy activities.

It has been argued that the globalisation of healthcare inputs has occurred as multi-national companies wield power to gain control of international health product markets using international regulatory mechanisms set up around the World Trade Organisation and the Trade in Intellectual Property Rights Treaty (TRIPS) (Mackintosh and Koivusalo, 2005). While IAVI increasingly stressed its emphasis on local ownership and that its role is to facilitate the development of local capacity in all areas related to AIDS vaccine research, there is no doubt that IAVI's facilitating role in the development of a Kenyan AIDS vaccine research policy environment complicates the issue. In fact it suggests a situation similar – but with a different starting point (neglected disease product development) – to that outlined by Petryna and colleagues (2005; 2006) in discussing the rise of clinical trials in Eastern Europe where "deliberations over the ethics of research in crisis-ridden areas are set against – even eclipsed by – the market ethics of industry scientists and regulators." (Petryna, 2005: 192)

However, at the same time, the policy environment in Kenya is further complicated by the emphasis placed on treatment over research activities, introduced in Chapter Four, which may relate to the changing focus of international health policy towards disease specific interventions rather than focusing on longer term sustainability. On numerous occasions by those inside and outside the Government of Kenya I was told that research and vaccines were not high on the country's health policy agenda. These were dominated instead by treatment of HIV/AIDS and service provision. I was told for example that an AIDS vaccine is not a reality yet and therefore "it is not yet discussed in programme corridors, only in research corridors" [Policy2]. However, discounting the fact that an AIDS vaccine might not be on the agenda because it was not available as yet, neither was research more generally. There appeared to be little co-ordination (although I was told this was in the process of changing) between the national HIV/AIDS coordinating body, the National AIDS Control Council (NACC), and research efforts while the national HIV/AIDS policy

had only one paragraph regarding research in it. I was told that NACC sends a representative to the HIV vaccine sub-committee meetings, that all HIV/AIDS research is supposed to receive a certificate of notification from them (to state that they have been notified of the research once a protocol has been approved by an ethics committee) and that a new NACC policy on HIV/AIDS research was being developed. However, even within this changing environment "you have to fight so much for an [research] activity to be supported" [Policy5].

In fact, these examples suggest that while, on the one hand, the international face of IAVI and its global partnership is seen as very much part of the move towards vertical top-down programming, on the other, on the ground in Kenya, the situation is less clear cut involving multiple power dynamics and includes a focus relating to international development objectives focusing on capacity building and sustainability. IAVI's international focus is couched within the movement towards a globalisation of healthcare inputs markets where the focus is on the market failure within neglected disease health product development which requires a private sector business model approach. However, on the ground in Kenya, IAVI has to engage in more traditional international development activities. IAVI has increasingly moved their clinical trial activities to developing countries such as Kenya, opened regional offices, become involved in training and equipping of staff for research activities and involved in care provision activities. All of which takes place within the context of existing alternative storylines on the ground in Kenya as exemplified by the discussion around treatment or prevention activities within the Government of Kenya.

The result is a tension between focusing on process and capacity building over outcomes or goal orientation and taking a short term over a long term perspective. The issue between emphasising long or short time frames is emphasised at a different point in the discussion I had with the IAVI manager I mentioned earlier:

> "That's another dilemma. We have two schools of thought. One is that we – speed is of the essence – we are here to find a vaccine, we are not a development agency to build capacity for its sake. So that's one side. On the other hand when we are asked when do you think a vaccine will be available the answer is no less than 10 years and to me 10 years is really a long term

> stay. So, I can't see how we can't be around for 10 years still renting a building, you know. And those 10 years, we haven't even stated counting the 10 years. We'll count from the day we get a truly efficacious vaccine that is now going into Phase III so it's never too late but really we have at least another 10 years. And so these are the two sides and the arguments continue. And while I'm on one side as you can guess, I'm always told to remember that IAVI is health for a specific time limited agenda, you know, that must be delivered soon, we mustn't be seen to be digging in." [IAVI1; emphasis added]

Thus, as has been stressed on several occasions within this thesis, the situation can be illustrated or stylised as one of a tension, moulded by competing and different operational storylines, within IAVI of focusing on the business model and the end product over issues of sustainability. There is the idea that IAVI is not an aid project on the one hand but that, as highlighted in Chapter Five, its own documents state capacity building is an important part of its work. As outlined above these tensions are part and parcel of the international policy partnership discourses that see PPPs as developing out of a focus on partnerships as a way to move forward with sustainability and capacity building within development assistance while also an increasing focus is placed on market forces with an emphasis on getting new products developed.

6.6 Beyond partnership

The complexity that the storylines and discourses create means that understanding how partnership and capacity building takes place, as per Chapters Four and Five, can only be properly understood when the institutional power and politics flows discussed in these chapters is taken in conjunction with the wider overarching discourses and operational level storylines. To fully understand the meso level institutional structures and interrelationships that are associated with what is defined as the 'IAVI partnership' in Kenya requires, as this Chapter has introduced, the consideration of a range of interconnecting forces, actors and relationships that are external to the IAVI partnership in Kenya but which influence and are influenced by the partnership activities. The IAVI partnership in Kenya is part of a greater

whole.[29] Understanding this greater whole is not simply about acknowledging the interplay between the macro and the micro (between local and international; theory and practice; discourse and storylines) but about understanding this interplay and how it becomes real to those involved (Mosse and Lewis, 2006b; Pieterse, 2001) as a result of a wider set of meso level structuring relationships and linkages. For example, I have made reference in previous chapters to a wider range of influences on partnership activities than simply what happens in the partnership amongst the main partnership actors. There are for instance the linkages between those involved in innovation or scientific research activities and those involved in healthcare. These take place within the IAVI partnership in Kenya but also extend to discussions within the wider country level AIDS vaccine research network. More specifically it is this interaction that is moulded by, reinforces and changes the alternative set of storylines that are dominant at the operational level.

To recognise the need to understand this interplay raises the question that I first asked in Chapter Four, as to where the IAVI partnership starts and finishes and whether is it possible to consider the IAVI partnership's activities in building capacity in health and innovation in isolation? If the IAVI partnership in Kenya is connected to a wider AIDS vaccine research network in the country, it not only becomes difficult to determine where the partnership starts and finishes but also where its capacity building activities start and finish.

As the previous chapters highlight IAVI can be seen as a parental partnership on the one hand and on the other a more nuanced network of actors coalescing around the AIDS vaccine research activities undertaken by the IAVI partnership members on the ground in Kenya, each with their own concerns and requirements. The list of actors is potentially never-ending as the consequences of IAVI's activities with its partners have impacts on more than just the immediate vicinity in which it undertakes its activities. For example, the negotiations that have taken place around the promotion

[29] In this section I do not aim to outline all the various elements of 'the greater whole' but to highlight the importance of acknowledging the wider influences on 'the Kenyan IAVI partnership' based on the findings of my study. As I have alluded to in previous chapters, 'the greater whole' is a fluid arrangement of actors, processes and cultures that change depending on the perspective and actors used as reference points.

of new regulatory pathways in Kenya – the creation of new research guidelines for AIDS vaccine research in particular – has knock on effects for the members of the regulatory agencies. These effects include the changing of their work activities and potentially increasingly their workloads particularly should this lead to the re-thinking of all research guidelines (an activity that I was told by several in IAVI has occurred in Uganda following its development of AIDS vaccine research guidelines).

The result is that how the IAVI partnership develops and evolves as well as its boundaries are determined by how these different actors interact and negotiate what is important and what is not and who wins the negotiations. IAVI's activities in Kenya cannot therefore be explained simply as the result of a dominant discourse around the role of the private sector and PPPs such as IAVI as the right mechanism simply to combat market failure. It would however also be wrong, from the opposite but equally singular notion, to consider IAVI simply as an example of a vertical top-down partnership that will have no positive impact on health or innovation in developing countries. IAVI's activities and its continued support result from a complex array of different storylines, discourses and movement along an organisational model/ cultural continuum. It is more of an organic, living structure than much of the literature (as outlined in the previous chapter) would give it credit for. In fact it involves more than one structure; there is IAVI as a NFP, the wider IAVI partnership at country level, an IAVI partnership at global level which has not been the focus of this thesis and, a wider AIDS vaccine research network in Kenya.

Based on the conclusions of Chapter Five, the opportunities for knowledge exchange, learning and capacity building go well beyond simply that between IAVI and the research organisations in Kenya despite these relationships being the centre of the IAVI partnership in Kenya. The IAVI partnership in Kenya cannot be considered in isolation of its surroundings. The IAVI partnership in Kenya is connected through its activities at the trial sites but also through its activities within a wider AIDS vaccine research system to what can be termed national and international networks or ' innovation systems' of healthcare and research.

Rather than simply conclude at this point by highlighting the complexity and interconnecting forces, actors and relationships, I shall now suggest a way to make sense of this complexity as recommended by Cornwall (2007). Going back to the food analogies given in Chapter Four it is insufficient to consider the IAVI partnership in Kenya's collaboration and capacity building processes simply by moving the focus of attention from the one-dimensional fried egg representation of the IAVI partnership to a three dimensional walnut whip concept. It is necessary to go beyond this to consider the packaging around the chocolate for a more multi-dimensional approach. In so doing the focus of attention changes from the IAVI partnership to considering the complexity of the process of activities and interactions around a common issue more generally, in this case AIDS vaccine research.

Therefore it may be more appropriate when thinking about the IAVI partnership and its activities on the ground in Kenya to move beyond value laden notions of partnerships and the limits of innovation systems thinking and consider the existence of various 'assemblages' (Ong and Collier, 2004) or networks of entities that are less bound by locality and more by their relationship with AIDS vaccine research activities. AIDS vaccine research can be seen as an example of a 'global form' (Ong and Collier, 2004), movable and dynamic phenomena that are solidified through relationships or assemblages. As such they are similar to the notion of 'boundary objects' (introduced in the previous chapter) as they are:

> "both plastic enough to adapt to local needs and constraints of the several parties employing them, yet robust enough to maintain a common identity across sites. They are weakly structures in common use and become strongly structures in individual-site use." (Bowker and Star, 1999: 297).

The benefit of such an approach is that it is free from a focus on institutional structures as a starting point (as per notions of partnership and innovation systems) and yet at the same time places an emphasis on the role of knowledge exchange and brokers that Chapter Five has highlighted is so important for understanding the process of interconnecting forces, actors and relationships that create collaboration and capacity building. Most importantly this approach is multidimensional and therefore crosses the micro and macro divide to allow understanding of the

operational level activities and their related discourses, storylines, cultures and organisational models.

IAVI, the IAVI partnership in Kenya and AIDS vaccine research means different things to different people. Ong and Collier (2004: 12) talk of an assemblage as "the product of multiple determinations that are not reducible to a single logic." Similarly, in Kenya, for IAVI's founder, Seth Berkley, the IAVI partnership mechanism is the best way to ensure a vaccine for AIDS is developed. Yet for others (such as some within the research organisations and IAVI) it is a way to promote clinical research activities to build up local research capacity. For another set of actors (including individuals in the research organisations, NGOs and IAVI's regional office) it is an opportunity to get ethics and rights on the agenda. While for a different set of actors (healthcare providers and individuals in IAVI and the research organisations) it is about working towards the strengthening of healthcare provision. And no doubt these are by no means the only reasons people are involved, support and promote IAVI and AIDS vaccine research in Kenya. These are however, the reasons that were most often highlighted by my research. None of these can be reduced to a single logic but they can coalesce around the 'global form' of AIDS vaccine research. This form is movable to the global or international level in relation to the way groups discuss and negotiate IAVI's place in AIDS vaccine research and the research itself, its funding etc. with a wider set of actors but this has not been an area I have specifically considered in this thesis. It is important to note at this point though that how AIDS vaccine research is considered internationally will have implications on how such activities take place on the ground in Kenya and how IAVI interacts with different actors in Kenya. For example, as I have already mentioned earlier in this thesis, it will be interesting to see the repercussions that the halting of Merck's international AIDS vaccine trial in September 2007 will have on IAVI's activities generally and in Kenya specifically. All these negotiations – the "debate and contest" – makes the assemblage of actors what it is (Collier, 2006: 400) and determines how AIDS vaccine research is taken up and played out.

For example, these negotiations are highly visible in the debate regarding whether IAVI's AIDS vaccine research activities should follow, what can be simplified to, either a business model or an international development model. The debate and contest between different actors determines whether IAVI should be a virtual pharmaceutical company, a NFP, or – as it appears to be – a hybrid of both. Similarly, negotiations within the assemblage are influential in determining the dominance of innovation and research within the IAVI partnership's activities on the ground in Kenya as opposed to emphasising more explicitly capacity building activities. Negotiations are also paramount in determining the change of heart with regards to healthcare provision within clinical trials and IAVI's role as a research or healthcare provider. These various negotiations make IAVI, the IAVI partnership and the more general AIDS vaccine research debate within the Kenyan policy network what it is. Considering these activities from the perspective of assemblages provides an opportunity to move beyond set organisational definitions and look at the real mechanisms of decision making to explain how AIDS vaccine research gains and maintains significance.

This thesis has highlighted how IAVI is made up of a network of multiple actors involved in AIDS vaccine research. How the IAVI partnership operates and what activities are undertaken are determined by the relations between these different actors and the negotiations that take place. The result is that IAVI and the IAVI partnership in Kenya are organic structures that are placed within a wider assemblage of actors that coalesce around AIDS vaccine research, a 'global form' being a movable and dynamic phenomenon that is solidified through relationships or assemblages.

The fluidity of the AIDS vaccine research assemblage is at odds, however, with current policy constructs that are used to promote the health innovation activities PDPs such as IAVI undertake. As I have discussed previously in this thesis, such PDPs are seen as examples of 'health innovation networks', a type of innovation system, where the emphasis is placed on creating the correct enabling environment (the creation of knowledge exchange and collaborative linkages) for the promotion of

innovative activity, in this case around AIDS vaccine research. However, the activities of the IAVI partnership also fit within other 'systems' constructs that have been developed in other (sometimes related) policy arenas: a health research system and the more general health system.

Yet, as discussed in Chapter Four, systems terms have the tendency to simplify the complexity of the extent, strength and dynamism of the linkages between actors within these networks, particularly as they often focus on the wider enabling environment and not on the actual workings of the systems themselves. However, thinking systemically – holistically even to take up Pieterse's notion mentioned in Section 6.3.2 – about who is involved and how AIDS vaccine research takes place including through the IAVI partnership is important both at the local (micro) level and the international (macro) level. It provides an opportunity to see a larger picture and to view the whole assemblage of actors and their negotiations providing a means of moving beyond discrete systems to develop more integrated policy.[30]

Integrated policy is necessary because, as the IAVI case study of this thesis shows, neither innovation nor health care activities happen in isolation. The activities of each 'system' are dependent on activities or actors in the other 'system' and the effects of each will ultimately impact the ability of the other system to operate. Considering the IAVI case study from the perspective of assemblages highlights how it is possible to move beyond starting points from individual actors to the starting point of the global form of AIDS vaccine research to gain a better idea of who and what is involved and how their interactions produce activity and outcomes such as different forms of capacity building.

[30] Recognising the discussion within anthropology and ethnography around the difficulties of obtaining 'holism' as defined as wholeness or awareness of all social context (c.f. Gellner and Hirsch, 2001; Thornton, 1988) I am specifically referring here to Pieterse's definition of the term 'holism'. Pieterse (2001: 131-133) places an emphasis on the "recombination of fragments" to make visible "what has been ignored, left out" to create a totality. His is a methodological use of the term towards the creation of a multidimensional study of development activities. As such, I put forward the concept of 'assemblages' as a methodological means of creating a new totality of view.

6.7 Conclusion

This chapter has outlined two distinct discourses as a way to illustrate, through simplicity, the complexity within a 'turn to partnership'. These have provided a means of understanding the different starting points to the issue of neglected disease product development and scientific research capacity which vie for attention particularly on the international health policy scene. I have situated the IAVI partnership in Kenya within these discourses and highlighted a number of different storylines that take place at the operational level of the partnership which are interlinked with the overarching discourses. I have highlighted the complex nature of the interplay between international policy around PDPs that is put forward (as per the introductory chapters) for their rise and continued promotion, and, the actual activities on the ground in Kenya. In particular, I have highlighted that it was not a simple case of international policy rhetoric, around a dominant overarching discourse of market failure and the rise of PDPs, being manifested within IAVI's activities and those of the wider partnership in Kenya. Specifically, this chapter has highlighted how international policy is played out on the ground; actors are influenced by this policy but in turn also manipulate and transform policy as is required. This interplay between the discourses and the operational storylines working on and within the IAVI partnership activities can be evidenced along a stylised organisational model continuum whereby different actors work within cultures that place their activities along the continuum. These cultures vie for control of the activities but are in their turn moulded by the needs and demands of the local environment through the operational storylines. Finally, I have discussed how the existence of and interplay between the discourse and storylines highlight the importance of not only looking at power and politics at the partnership level but also the wider influences on these in order to understand the complexity that results. I have discussed the use of Ong and Collier's notion of 'assemblages' and 'global forms' as one way of understanding this complexity.

In so doing I have addressed all three main themes of this thesis. This chapter has specifically addressed the second thesis theme of the linkage of innovation and

health through a discussion of the interplay and interconnection of various different actors and thus the difficulty of separating activities into separate silos such as innovation or health. For AIDS vaccine development to take place it requires multiple linkages and connections both between the members of the IAVI partnership in Kenya but also with others external to this partnership and who are members of other forms of network or 'system'. Similar to the conclusions of Chapter Four and addressing the first thesis theme on collaboration I have highlighted the multiplicity of interactions that are involved in the collaboration and the difficulty of placing borders around a system such as a partnership.

The chapter has also discussed the third thesis theme of capacity building although in a less overt manner. The chapter has focused on the importance of meso level organisational and institutional structures within the IAVI partnership in Kenya. However, I have also discussed the need for a focus on process in order to go beyond these to consider more implicit structuring relationships and linkages that occur through the promoting and competition between discourses and storylines. The chapter concludes with an acknowledgement of the need to understand the complexity that is the process of AIDS vaccine development not just within the IAVI partnership in Kenya but as a whole. This suggests that far from being too ambitious and too wide as I suggest in Chapter One, the definition of process capacity that I have used in this thesis is perhaps not wide enough. While my definition of process capacity includes the macro enabling environment, my consideration of this environment is with regards to that which enables the IAVI partnership in Kenya directly. As such it does not consider influences on AIDS vaccine development more generally. Based on the conclusions of this chapter, such a focus would not get to grips with the complexity of the wider number of interconnecting forces, actors and relationships that in fact impact, and are also affected by, the work that takes place in the IAVI partnership in Kenya.

Finally, this chapter has also discussed a fourth resulting theme that has become apparent as the thesis has progressed regarding the relationship between the micro, macro and meso levels of activity. This chapter has highlighted the role of the meso or organisational and institutional level as a way of acting as the link between the

interconnecting forces, actors and relationships to ensure AIDS vaccine research activities take place. This is because of its strong function, as outlined in Chapter Five, of being integral to the process of an activity. Building strong process capacity through the creation of multiple links inside and outside the IAVI partnership in Kenya are essential for AIDS vaccine research activities by IAVI and its partners in Kenya. At the same time it has also discussed the related issue of the interconnection between the micro and macro level. International development activities such as scientific research partnerships like the IAVI partnership in Kenya are a complex mix of connections across different levels and of forces, actors and relationships. It has discussed the difficulty of separating the local and the international, theory and practice or discourse and storylines. Understanding how the IAVI partnership in Kenya works requires an acknowledgement of the interplay between the macro and the micro as a result of meso (organisational) level activities. Creating a partnership does not automatically lead to the building of capacity to strengthen developing country health and innovation. It requires an understanding of the complexity of processes involved to move beyond value laden notions of partnership.

Chapter Seven
Conclusion

7.1 Thesis review

My thesis is built on two starting points which I outlined in Chapter One and which relate to three thesis themes that I then discussed in Chapter Two. It is from these that my research questions developed. The main theme and starting point for my PhD was the rise of PDPs as a collaborative form to incentivise health product development of medicines (drugs, vaccines and diagnostics) for neglected diseases. I outlined in these two chapters the lack of attention placed on the process of partnership in these discussions of the rise of PDPs and therefore my first research question asked how does collaboration within a PDP, IAVI, take place in Kenya? I outlined how I was particularly interested in knowing whether there is collaboration between those involved in healthcare and those involved in the health innovation activities of the clinical trial sites in Kenya. This is the second theme and starting point for my thesis. In Chapter One I introduced, and discussed in more depth in Chapter Two, the lack of recognition within policy circles of the interaction between these two fields of activity. Thus my second research question was does interaction occur between these two fields and what type of interaction takes place? Building on work from my MSc dissertation I discussed how knowledge exchange is seen, within the innovation field, as strongly linked to the quality and effectiveness of such collaborative activity. Focusing on the role of knowledge exchange as a form of capacity building, I discussed in these two introductory chapters, the ability of collaborative activity to build organisational processes to create stronger institutions and enabling environments by increasing knowledge exchange. I also discussed a tension within the international development arena regarding process activities and the change this has had on the type of capacity building activities promoted. As

such, in this third theme of capacity building, my research question related to the type of capacity building that takes place in the IAVI partnership in Kenya.

In the last introductory chapter (Chapter Three) I outlined my research methods. As I outlined in this methodology chapter and reiterate towards the end of Chapter Four, this thesis has been able to critically analyse the issues of collaboration and capacity building because it used an interdisciplinary approach that brings together ideas from within the literature on the ethnography and anthropology of development with innovation systems thinking. The marrying of this latter more instrumentalist approach, focusing on collaboration and knowledge exchange as requirements for successful innovation, with a highly normative approach working within the 'spirit of ethnography' provides a means to critically examine in detail and in depth the relations that take place around the IAVI partnership in Kenya.

This critical discussion of the type of partnership that takes place in Kenya around IAVI's activities starts in Chapter Four with a critically review of some of the concepts of partnership that have been put forward. In particular I discussed the difficulties of defining 'true partnership' which assumes joint ownership and mutuality. I defined an alternative form of partnership, 'effective partnership', which acknowledges the benefits gained from partnerships within the context of these unequal power relations. I then outlined findings from my empirical data that highlight the existence within the Kenyan IAVI partnership of a variety of different partnership types (bottom-up, top-down and parental) and how the partnership manifests itself differently depending on whether it is examined in terms of the collaboration between IAVI and the public sector research organisations in Kenya of KAVI and KEMRI-CGMRC or as a wider grouping of actors. The partnership is more than a binary relationship between 'them vs. us' as development assistance projects, particularly science based ones, have been perceived. In understanding the partnership I argued that it is important to embrace the complexity that exists and outlined how this provides evidence of the difficulty of defining the IAVI partnership in Kenya as a true partnership although it does not rule out the possibility that it may be an effective partnership.

In this chapter I then discussed the possibilities to move beyond value-laden notions of partnership in binary terms (top-down, bottom-up and parental mother to child) by taking an interdisciplinary focus on the processes of partnership to consider what makes partnership 'facilitatory'. As I mentioned above, this interdisciplinary focus brings together an ethnographic rationale with innovation systems ideas. Thus, in Chapter Four I discussed how the IAVI partnership in Kenya has characteristics similar to an innovation system (and is increasingly discussed in health research and innovation policy circles in this way) because of the role different actors have as conduits of information. These activities were highlighted due to the critical ethnographic perspective I took to study the collaborative activities. In so doing, in this chapter, I introduced into the thesis a discussion on knowledge exchange as a result of collaborative activity.

This discussion on knowledge exchange is taken up in more depth in Chapter Five. Chapter Five discussed the capacity building activities, including those based on knowledge exchange, that take place in the IAVI partnership in Kenya. In this chapter I distinguished between different types of capacity building and recent changes in attitude towards capacity building in the fields of international development and health research. I specifically made the distinction between tangible capacity building in the form of training and resource provision and less tangible, knowledge based forms of capacity building which I termed 'process capacity'. I divided process capacity into two types. The first relates to institutional and meso level capacity building around strengthening of organisational processes and increased knowledge exchange and learning. The second type of process capacity relates to macro level strengthening of enabling environments. I discussed how these different types of capacity take place within the IAVI partnership in Kenya. I outlined the lack of overt emphasis placed on process forms of capacity, particularly meso level institutional capacity, which means IAVI ends up 'doing development without doing development' to use Chataway's term. I argued that focusing on process capacity provides a way to highlight the linkages between actors and activities in the areas of innovation and healthcare that are often viewed

separately. More specifically, the role of meso level capacity in particular, highlights the systemic nature of innovation activities, the range of actors involved and the importance of considering AIDS vaccine research activities in a holistic manner.

Considering AIDS vaccine research in a holistic manner is the central focus of the last main thesis chapter, Chapter Six. In this chapter I situated the IAVI partnership in Kenya within the wider macro level discourses and micro level storylines that influence, and are influenced by, activities on the ground within the partnership. In so doing I highlighted the multitude of actors involved and the difficulty of bounding analysis of the partnership activities across time and space. The activities that occur in Kenya within the IAVI partnership take place along an organisational continuum reflecting the differing discourses and storylines that dominate at different times. The result is a complexity of actors, forces and relationships that impacts the partnership activities and which also extends beyond the Kenyan IAVI partnership. I outlined how this strengthens the argument that it is difficult to see the Kenyan IAVI partnership in binary terms of top-down, bottom-up or parental partnership and that, as a result, it may be more useful to move beyond partnership notions. In moving this discussion forward, I introduced the notion of 'assemblages' and the need to view the IAVI partnership in Kenya as part of a wider assemblage of actors, forces and relationships that coalesce around AIDS vaccine research more generally. I concluded by discussing how this provides a means to more fully understand the knowledge exchange and linkages that are so important for understanding activities that make up the IAVI partnership in Kenya.

7.2 Issues raised

As the above review of my thesis highlights, the IAVI partnership in Kenya has not one, but multiple, collaborative forms which includes interaction between the fields of innovation and healthcare. This interaction is not confined to what I have defined as 'the Kenyan IAVI partnership' but involves collaborative activity and knowledge exchange beyond this. Collaborative activity and knowledge exchange are

themselves forms of capacity building and these take place within the IAVI partnership in Kenya. These however, while important, receive less attention by those involved within the partnership in discussions of capacity building activities than more tangible forms of capacity building around training activities and infrastructural resource provision. These findings, in answering my research questions, have given rise to a fourth theme regarding the relationship between the macro, micro and meso levels. It has also highlighted two connecting issues that have also emerged as the thesis has progressed. I shall now briefly discuss this emerging theme and the two connecting issues in a little more depth. This will include a discussion of the questions that they raise and starting points for future research. The thesis overview map given in Chapter One (Figure 1.2) provides a graphic illustration of this fourth theme and the connecting issues and their origins in the initial themes and issues of this thesis.

7.2.1 Emerging Theme: Macro, micro and meso interactions

In Chapter Six I discussed the interplay between international (policy) level discourses and country level operational storylines. I outlined how this interplay mirrors discussions within social theory regarding the relationship between the macro-social and the micro-social. The thesis has highlighted how this relationship between the macro and the micro can also be defined in terms of activities occurring at an individual (micro) level and those occurring at a group (macro) level. This thesis therefore highlights the difficulties of isolating discussion to only one of these levels and the need for more holistic or systemic analysis.

Chapter Four in discussing the relationship between the IAVI partnership in Kenya and innovation systems thinking is the first chapter that considered the need for a holistic or systemic approach to studying AIDS vaccine research activities due to the multiple actors and multiple levels involved. Chapter Five also highlighted the interplay between the macro and the micro but as a result of introducing the role of the meso or organisational level as a linkage between the macro and micro level activities. Chapter Five highlighted the importance of an intermediary meso level set of activities that provided the important connecting point between the work of

individual nurses, doctors or ministry officials and the success of the IAVI partnership as a whole. In particular, through this thesis I have come to realise the importance of what could be termed the 'social technology', the organisational linkages that hold everything together based around the role of the meso level as a connecting node that creates the enabling environment (collaborative linkages and knowledge exchange) required for successful completion of tasks. Thus, this thesis has highlighted how the issue of health innovation for neglected diseases can not simply be seen in terms of overcoming just 'market failures'. It is important to also acknowledge the 'social failures' that occur when insufficient attention is given to the collaborative and knowledge exchange activities, at the meso level, that make up process capacity.

7.2.2 Emerging Issue I: Benefits from collaboration

The first emerging connecting issue relates to how different groups benefit from being involved in collaboration with IAVI. This developed out of the connections made between my discussions of partnership and capacity building activities in Chapters Four and Five. In both chapters I have highlighted how it is possible for an objective of the partnership activities to be not only working towards development of an effective vaccine, but also, the building of better processes for the creation of longer term capacity and participation in research activities. If, as my thesis highlights, different groups involved in the IAVI partnership in Kenya benefit from the collaborative process and the knowledge exchange that occurs, this raises questions regarding whether it is useful to evaluate PDPs such as IAVI by focusing on process outcomes (such as increased knowledge exchange) rather than simply on measures of product development? Areas of further research therefore could look at this in more detail to discuss if there are certain process related outcomes that should be focused on (such as knowledge exchange) over others and how these could be integrated into more general country level health research and innovation data collection.

7.2.3 Emerging Issue II: Complexity

The second emerging issue relates to complexity and its evidence in numerous aspects of this discussion. In particular, complexity appears in two major places as a result of my focus on the linkages between innovation and healthcare actors and capacity building. Firstly, it appears in my discussions of the form that the IAVI partnership takes. The IAVI partnership in Kenya cannot be thought of in simply binary terms of bottom-up, top-down and parental mother-child but involves multiple actors who interact in many different ways and with no single power or politics dynamic. This includes actors within the healthcare arena and not simply those involved in health innovation activities around the clinical trial sites in Kenya. Secondly, and related to this, it appears in my discussion of the levels of activity at which the partnership activities take place. It is not possible to consider the IAVI partnership in Kenya at only one level of activity. The members of the IAVI partnership in Kenya work in, and with others, at both the macro and micro levels which themselves can be defined in a variety of ways.

In Chapter Six, rather than leave the conclusion of my thesis as that of highlighting this complexity, I introduced the concept of 'assemblages'. I discussed how this provides one way to move forward with thinking about process factors. It provides a means of linking the macro and the micro as the concept places an emphasis on the meso organisational level defined more broadly then in terms of the operational activities of the IAVI partnership in Kenya. This concept may provide a means of moving beyond subjective and value-laden concepts such as 'partnership', but also goes beyond the limitations of 'systems' thinking discussed in Chapter Four, by taking as a focus the linkages between actors around particular phenomena. However, to truly discuss the potential of the concept of assemblages to the area of AIDS vaccine research requires a research project in its own right.

Finally, this thesis has highlighted the value of integrating ideas from within innovation systems thinking (from which the focus on collaborative and knowledge exchange activity came from) with a critical and normative ethnographic or anthropological rationale to consider the complexity created. To move beyond this,

to consider the implications of such an interdisciplinary approach for policy on health innovation of medicines (drugs, vaccines and diagnostics) for neglected diseases, is an obvious next step.

7.3 Conclusion

I have outlined above a review of my thesis findings, together with a number of issues and areas of future research that have developed out of my research into the collaborative and capacity building activities of the IAVI partnership in Kenya. My thesis has asked old questions around the role of collaboration, capacity building and knowledge exchange in new ways and as such begins a discussion towards the development of new theory around health innovation in relation to health product development of new medicines for neglected diseases. My thesis asks questions and raises issues around how collaborative activity builds capacity in developing country health innovation activities. In particular, my thesis addresses the role of process capacity, less tangible knowledge-based skills and capabilities, in aiding AIDS vaccine research in Kenya conducted by IAVI and its partners. This research thus provides not only a useful source of information for IAVI but also is relevant for researchers and practitioners involved in neglected disease production development, health innovation and health research more generally.

References

aidsfondet 'Funding AIDS Vaccine research ', www.aidsfondet.dk.
Alsop, R. and Farrington, J. (1998), 'Nests, Nodes and Niches: A System for Process Monitoring, Information Exchange and Decision Making for Multiple Stakeholders', *World Development*, 26, 2, 249-260.
Alvares, C. (1993), 'Science', *in* W. Sachs (ed.), *The Development Dictionary*, London, Zed Books.
Archibugi, D. and Bazzarri, K. (2004), 'Committing to Vaccine R&D: A Global Science Policy Priority', *Research Policy*, 33, 10, 1657-1671.
Baaz, M. E. (2005), *Paternalism of Partnership: A Post-Colonial Reading of Identity in Development Aid*, London, Zed Books.
Bailey, K. D. (1978), *Methods of Social Research*, New York, Free Press.
Barder, O., Kramer, M. and Levine, R. (2005), *Making Markets for Vaccines: Ideas to Action*, Washington D.C., Center for Global Development.
Batson, A. (1998), 'Win-win interactions between the public and private sectors', *Nature Medicine*, 4, 3, 487-491.
Batson, A. (2002), 'The costs and economics of modern vaccine development', *Dev Biol (Basel)*, 110, 15-24.
Batson, A. and Ainsworth, M. (2001), 'Private investment in AIDS vaccine development: obstacles and solutions', *Bull World Health Organ*, 79, 8, 721-7.
Bazzoli, G. J., Stein, R., Alexander, J. A., Conrad, D. A., Sofaer, S. and Shorte, S. M. (1997), 'Public-Private Collaboration in Health and Human Service Delivery: Evidence from Community Partnerships', *Millbank Quarterly*, 75, 4, 533-561.
Bennett, S., McPake, B. and Mills, A. (1997), 'The Public/Private Mix Debate in Health Care', *in* S. Bennett, B. McPake and A. Mills (eds.), *Private Health Providers in Developing Countries: Serving the Public Interest*, London, Zed Books.
Berg, M. (1998), 'Order(s) and Disorder(s): of Protocols and Medical Practices', *in* M. Berg and A. Mol (eds.), *Differences in Medicine: Unravelling Practices, Techniques, and Bodies*, London, Duke University Press.
Berkley, S. (2003), 'Thorny issues in the ethics of AIDS vaccine trials', *The Lancet*, 362, 9388, 992.
Berkley, S. (2006), 'Ending an Epidemic: The International AIDS Vaccine Initiative Pioneers a Public-Private Partnership', *Innovations*, Winter 2006, 52-66.
Bernard, H. R. (2006), *Research Methods in Anthropology: Qualitative and Quantitative Approaches* (4th Edition), Lanham, MD, Almamira Press.
Bessant, J. and Tsekouras, G. (2003), 'Developing Learning Networks', *UKWON Working Paper Number 9*, Brighton, University of Brighton.
Blume, S. (1992), *Insight and Industry: On the Dynamics of Technological Change in Medicine*, Cambridge, MA., Massachusetts Institute of Technology Press.
Bowker, G. and Star, S. L. (1999), *Sorting Things Out: Classifications and Its Consequences*, Cambridge, MA, MIT Press.

Bryman, A. (1988), *Quantity and Quality in Social Research*, London, Unwin.
Bryson, J. M. and Crosby, B. C. (1992), *Leadership for the common good - tackling public problems in a shared power world*, San Francisco, Jossey-Bass.
Burawoy, M., Burton, A., Ferguson, A. A. and Fox, K. J. (1991), *Ethnography Unbound: Power and Resistance in the Modern Metropolis*, Berkeley, University of California Press.
Burri, C. (2004), 'High Time to Take Action: Research on Neglected Diseases', *Bulletin of Medicus Mundi Switzerland*, 92.
Burt, R. S. (2002), 'The Social Capital of Structural Holes', *in* M. F. Guillén, R. Collins, P. England and M. Meyer (eds.), *The New Economic Sociology: Developments in an emerging field*, New York, Russell Sage Foundation.
Buse, K. (2004), 'Governing Public-Private Infectious Disease Partnerships', *Brown Journal of World Affairs*, 10, 2, 225-242.
Buse, K. and Harmer, A. M. (2004), 'Power to the Partners? The Politics of Public-Private Health Partnerships', *Development*, 47, 2, 49-56.
Buse, K. and Harmer, A. M. (2007), 'Seven habits of highly effective global public-private health partnerships: practice and potential', *Soc Sci Med*, 64, 2, 259-71.
Buse, K. and Walt, G. (2000a), 'Global public-private partnerships: Part I--A new development in health?' *Bull World Health Organ*, 78, 4, 549-61.
Buse, K. and Walt, G. (2000b), 'Global public-private partnerships: Part II--What are the health issues for global governance?' *Bull World Health Organ*, 78, 5, 699-709.
Buse, K. and Walt, G. (2002), 'Globalisation and multilateral public-private partnerships: issues for health policy', *in* K. Lee, K. Buse and S. Fustukian (eds.), *Health Policy in a Globalising World*, Cambridge, Cambridge University Press.
Buse, K. and Waxman, A. (2001), 'Public-private health partnerships: a strategy for WHO', *Bull World Health Organ*, 79, 8, 748-54.
Bustreo, F., Harding, A. and Axelsson, H. (2003), 'Can developing countries achieve adequate improvements in child health outcomes without engaging with the private sector?' *Bull World Health Organ*, 81, 886-894.
Caines, K. (2004), 'Global Health Partnerships and Neglected Diseases', London, DFID Health Resource Centre.
Caines, K., Buse, K., Carlson, C., de Loor, R.-M., Druce, N., Grace, C., Pearson, M., Sancho, J. and Sadanandan, R. (2004), 'Assessing the Impact of Global Health Partnerships', London, DFID Health Resource Centre.
Carlsson, B. and Stankiewicz, R. (1991), 'On the nature, function and composition of technological systems', *Journal of Evolutionary Economics*, 1, 93-118.
Castells, M. (1996), *The Rise of the Network Society*, Malden, MA., Blackwell.
Chataway, J. (2005), ' 'The International AIDS Vaccine Initiative (IAVI): Is it Getting New Science and Technology to the World's Neglected Majority?'', London School of Economics.
Chataway, J. and Allan, T. (2000), 'Industry and Development: Prospects and Dilemmas', *in* T. Allan and T. Thomas (eds.), *Poverty and Development in the Twenty-first Century*, Oxford, Open University Press.
Chataway, J., Brusoni, S., Cacciatori, E., Hanlin, R. and Orsenigo, L. (2007), 'The International AIDS Vaccine Initiative (IAVI) in a changing landscape of vaccine development: a public private partnership as knowledge broker and integrator', *European Journal of Development Research*, 19, 1, 100-117.

Chataway, J., Chaturvedi, K., Hanlin, R., Mugwagwa, J., Smith, J. and Wield, J. (2007), 'Building the Case for National Systems of Health Innovation', *A Background Policy Paper prepared for NEPAD in advance of the AMCOST meeting and the African Summit January 2007*.
Chataway, J. and Smith, J. (2007), 'Participation, Communication and Innovation: Thinking about the International AIDS Vaccine Initiative', *IDS Bulletin*, 38, 5.
Chataway, J. C. and Smith, J. (2006), 'The International AIDS Vaccine Initiative (IAVI): Is it Getting New Science and Technology to the World's Neglected Majority?' *World Development*, 34, 1, 16-30.
Child, J. and Rodrigues, S. (1996), 'The role of social identity in the international transfer of knowledge through Joint Ventures', *in* S. R. Clegg and G. Palmer (eds.), *The Politics of Management Knowledge* London, Sage.
Clark, N. (1985), *The Political Economy of Science and Technology*, London, Blackwell.
Clark, N. (2000), 'Innovation Systems Institutional Change and the New Knowledge Market: Implications for Third World Agricultural Development', *Strathclyde Papers in Economics 2000/13*.
Clark, N. (2006), 'Application of the Innovation Systems Perspective in the African Higher Education Sector: Experiences and Challenges', *The Innovation Africa Symposium*, Kampala, Uganda.
Coarse, R. (1973), 'The nature of the firm', *Economica*, 4, 386-405.
Cohen, W. M. and Levinthal, D. A. (1990), 'Absorptive Capacity: A New Perspective on Learning and Innovation', *Administrative Science Quarterly*, 35, 128-152.
Collier, S. J. (2006), 'Global Assemblages', *Theory, Culture and Society*, 23, 2-3, 399-401.
Commission for Health Research for Development (1990), 'Health Research: Essential Link to Equity in Development', New York.
Commission for Macroeconomics and Health (2001), 'Macroeconomics and Health: Investing in health for economic development', Geneva, World Health Organisation.
Cornwall, A. (2007), 'Buzzwords and fuzzwords: deconstructing development discourse', *Development in Practice*, 17, 4-5, 471-484.
Cornwall, A. and Brock, K. (2005), 'Beyond Buzzwords: "Poverty Reduction", "Participation" and "Empowerment" in Development Policy', *Overarching Concerns: Programme Paper Number 10*, United Nations Research Institute for Social Development.
Crewe, E. and Harrison, E. (1998), *Whose Development? An Ethnography of Aid*, London, Zed Books.
Csazzar, M. and Lal, B. (2004), 'Improving Health in Developing Countries', *Issues in Science and Technology*, 2004, Fall.
Das, T. K. and Teng, B. (2003), 'Partner analysis and alliance performance', *Scandinavian Journal of Management*, 19, 279-308.
Davey, S., Jupp, S. and Mauroux, C. (eds.) (2004), *The 10/90 report on health research 2003-2004*, Global Forum for Health Research, Geneva.
de Francisco, A. and Matlin, S. A. (2006), 'Monitoring Financial Flows for Health Research 2006: The changing landscape of health research for development ', Geneva, Global Forum for Health Research.

de Jong, A. (1996), 'Inter-organisational collaboration in the policy preparation process', *in* C. Huxham (ed.), *Creating Collaborative Advantage*, London, Sage.
de Savigny, D. (2004), 'Health Systems and Malaria: Some Perspectives, Trends, and Implication for Malaria Vector Control and Personal Protection', *in* WHO Study Group on Malaria Vector Control and Personal Protection (ed.), *Background Paper*.
DFID (2007), 'DFID health strategy: Working together for better health', *in* DFID (ed.), Crown.
DiMaggio, P. (1997), 'Culture and Cognition', *Annual Review of Sociology*, 23, 263-287.
Dodd, R., Schieber, G. and Cassells, A. (2007), 'Aid effectiveness and health: Challenges to achieving and demonstrating the effectiveness of aid in the health sector', *WHO Making Health Systems Work Working Paper No. 9*, Geneva, World Health Organisation.
Eden, C. and Spender, J. C. (1998), *Managerial and Organizational Cognition*, London, Sage.
Edquist, C. (1997), *Systems of Innovation: Technologys, Institutions and Organisations*, London/ Washington, Pinter.
Eisner, E. (1981), 'On the differences between scientific and artistic approaches to qualitative research', *Educational Research*, 10, 4, 5-9.
Elston, M. A. (1997), *The Sociology of Medical Science and Technology*, London, Blackwells.
Engberg, L. A. (2002), 'Book Review: Public-private partnerships - Theory and Practice in International Perspective', *Public Administration*, 80, 3, 601-604.
England, S. (2000), 'Pushing and Pulling HIV/AIDS Vaccines', *IAVI/IAEN Internet Forum on Economics of AIDS Vaccines*.
Escobar, A. (1995), *Encountering development: The making and unmaking of the Third World*, Princeton, Princeton University Press.
Estava, G. (1992), 'Development', *in* W. Sachs (ed.), *Development Dictionary: A Guide to Knowledge as Power*, London, Zed Books.
Fagan, G. H. (1999), 'Cultural Politics and (post) Development Paradigm(s)', *in* R. Munck and D. O'Hearn (eds.), *Critical Development Theory: contributions to a new paradigm*, London, Zed Books Ltd.
Fairhead, J., Leach, M. and Small, M. (2006), 'Where techno-science meets poverty: medical research and the economy of blood in The Gambia, West Africa', *Soc Sci Med*, 61, 3, 709-719.
Ferguson, J. (1990), *The anti-politics machine : "development", depoliticization, and bureaucratic power in Lesotho* Cambridge, Cambridge University Press.
Field, J. (2003), *Social Capital*, London, Routledge.
Fine, B. (2001), *Social Capital versus Social Theory: Political Economy and Social Science at the Turn of the Millennium*, London, Routledge.
Fitzgerald, D. W., Papea, J. W., Wasserheita, J. N., Countsa, G. W. and Coreya, L. (2003), 'Provision of treatment in HIV-1 vaccine trials in developing countries', *The Lancet*, 362, 9388, 993-994.
Fitzgerald, D. W. and Wassuna, A. (2005), 'Away from exploitation and towards engagement: An ethnical compass for medical researchers working in resource-poor countries', *Journal of Law, Medicine and Ethics*, 33, 3, 559-565.
Flyvberg, B. (2001), *Making Social Science Matter*, Cambridge, Cambridge University Press.

Foucault, M. (1972), *The Archaeology of Knowledge*, Great Britain, Tavistock.
Fowler, A. (1991), 'Building partnerships between Northern and Southern development NGOs: issues for the 1990s', *Development in Practice*, 1, 1, 5-18.
Fox-Rushby, J. M., Kaddar, M., Levine, R. and Brenzel, L. (2004), 'The economics of vaccination in low and middle income countries', *Bull World Health Organ*, 82, 9, 640.
Fox, D. J. (1998), *An Ethnography of Four NGOs*, Lewiston, NY, The Edwin Mellen Press.
Fox, J. (2007), 'The uncertain relationship between transparency and accountability', *Development in Practice*, 17, 4-5.
Freeman, C. (1982), *The economics of industrial innovation* (2nd Edition), London, Pinter.
Freeman, C. (1987), *Technology Policy and Economic Performance: Lessons from Japan*, London, Pinter.
Freeman, C. (2003), 'Policies for Developing New Technologies', *Working Paper No. 98*, SEWPS, SPRU.
Freeman, P. and Miller, M. (2000), 'Scientific Capacity Building To Improve Population Health: Knowledge as a Global Good'.
Freeman, R. E. (1984), *Strategic management: a stakeholder approach*, Boston, MA., Pitman.
Gardner, K. and Lewis, D. (1996), *Anthropology, development and the post-modern challenge* London, Pluto.
Gardner, K. and Lewis, D. (2000), 'Dominant Paradigms Overturned or 'Business as Usual'? Development Discourse and the White Paper on International Development', *Critique of Anthropology*, 20, 1, 15-29.
Geertz, C. (1973), *The interpretation of cultures : selected essays*, New York, Basic Books.
Geissler, P. W. and Pool, R. (2006), 'Editorial: Popular concerns about medical research projects in sub-Saharan Africa – a critical voice in debates about medical research ethics', *Trop Med Int Health*, 11, 7, 975–982.
Gellner, D. N. and Hirsch, E. (2001), *Inside Organisations: Anthropologists at work*, Oxford, Berg.
Gerring, J. (2004), 'What is a Case Study and What is it Good for?' *American Political Science Review*, 98, 2, 341-354.
Glaser, B. and Strauss, A. (1967), *The Discovery of Grounded Theory*, Chicago, Il., Aldine.
Goodard, M. (2003), 'Regulation in healthcare markets', *Journal of Health Services Research and Policy*, 8, 4, 193-195.
Granovetter, M. (1973), 'The Strength of Weak Ties', *American Journal of Sociology*, 78, 6, 1360-1380.
Gray, D. E. (2004), *Doing Research in the Real World*, London, Sage.
Griffiths, D. and Boisot, M. (2000), 'Are There Any Competencies Out There? Identifying and Using Technical Competencies', *in* J. Tidd (ed.), *From Knowledge Management to Strategic Competence: Measuring Market and Organisational Innovation* London, Imperial College Press.
Hajer, M. A. (1997), *The politics of environmental discourse : ecological modernization and the policy process* Oxford, Oxford University Press.
Hajer, M. A. (n.d.), 'Methods'.

Hancock, T. (1998), 'Caveat Partners: reflections on partnership with the private sector', *Health Promotion International*, 13, 193-195.
Hanlin, R. (2006), 'Increasing knowledge flow by linking innovation and health - the case of SAAVI', *Genomics, Policy and Society*, 2, 3, 37-48.
Hanlin, R. (2007), 'Knowledge capacity and sustainable development: the case of South African HIV Vaccine Development', *International Journal of Technology Management and Sustainable Development*, 6, 1, 55-66.
Hardon, A. (2001), 'Immunization for all? A critical look at the first GAVI partners meeting', *HAI-Lights*, HAI Europe.
Hardon, A. and Blume, S. (2005), 'Shifts in global immunization goals (1984-2004): unfinished agendas and mixed results', *Soc Sci Med*, 60, 345-356.
Hargadon, A. and Sutton, R. I. (1997), 'Technology Brokering and Innovation in a Product Development Firm', *Administrative Science Quarterly*, 42, 4, 716–749.
Harper, I. (2005), 'Interconnected and interinfected: DOTS and the stabilisation of the tuberculosis control programme in Nepal', *in* D. Mosse and D. Lewis (eds.), *The Aid Effect: Giving and Governing in International Development*, London, Pluto.
Harris, E. and Tanner, M. (2000), 'Health Technology Transfer', *British Medical Journal*, 321, 30 September 2000, 817-820.
Harrison, D. (2001), 'Health research: an essential tool for achieving development through equity', *in* V. Neufeld and N. Johnson (eds.), *Forging links for health research: Perspectives from the Council on Health Research for Development*, Ottawa, International Development Research Centre.
Haugerud, A. (1995), *The Culture of Politics in Modern Kenya*, Cambridge, Cambridge University Press.
Hawe, P., Noort, M., King, L. and Jordens, C. (1997), 'Multiplying health gains: the critical role of capacity-building in health promotion', *Health Policy*, 39, 29-42.
Healy, T. (2001), 'Networks and social norms can be good for business: the role of social capital in organisations', *Social Capital: interdisciplinary perspectives workshop*, University of Exeter.
Hecht, R. M., Becker, J. and Roca, E. (2006), 'AIDS Vaccine Research Today - A Deeper Partnership Between Countries', *Global HealthLink*, 1 May 2006, 138.
Hecht, R. M. and Shah, R. (2006), 'Recent Trends and Innovations in Development Assistance for Health', *in* D. T. Jamison, J. G. Breman, A. R. Measham, G. Alleyne, M. Claeson, D. B. Evans, P. Jha, A. Mills and P. Musgrove (eds.), *Disease Control Priorities in Developing Countries* (2nd Edition), New York, Oxford University Press.
Hewitt, T. (2000), 'A Hybrid or a Third Way? Contemporary thinking on inter-organizational relationships', *in* D. Robinson, T. Hewitt and J. Harriss (eds.), *Managing Development: Understanding inter-organizational relationships*, Buckingham, Open University.
High-Level Forum on the Health MDGs (2005), 'Best Practice Principles for Global Health Partnership Activities at Country Level', Paris.
Hirschmann, A. (1970), *Exit, Voice and Loyalty: Responses to Decline in Firms, Organizations and States*, Cambridge, MA, Harvard University Press.
HIV Vaccines and Microbicides Resource Tracking Working Group (2006), 'Adding it all up: Funding for HIV Vaccine and Microbicide Development, 2000 to 2005'.

Honoré, A. Y. (2002), 'Diasporas, Brian Drain and Return', *African Societies*, 2002, 2.
Horton, D., Alexaki, A., Bennett-Lartey, S., Brice, K. N., Campilan, D., Carden, F., de Souza Silva, J., Duong, L. T., Khadar, I., Boza, I. T., Muniruzzaman, I. K., Perez, J., Chang, M. S., Vernooy, R. and Watts, J. (2003), 'Evaluating capacity development: experiences from research and development organizations around the world', The Hague, International Service for National Agricultural Research (ISNAR), International Development Research Centre (IDRC), ACP-EU Technical Centre for Agricultural and Rural Cooperation (CTA).
Hotez, P. J., Molyneux, D. H., Fenwick, A., Kumaresan, J., Sachs, S. E., Sachs, J. D. and Savioli, L. (2007), 'Control of Neglected Tropical Diseases', *N Engl J Med*, 357, 10, 1018-1027.
Hovland, I. (2003), 'Knowledge Management and Organisational Learning: An International Development Perspective: An Annotated Bibliography', *ODI Working Paper 224*, London, Overseas Development Institute.
Huxham, C. (1996), *Creating Collaborative Advantage*, London, Sage.
IAVI (2004), 'Developing and Delivering and AIDS Vaccine: Issues and Answers', *Policy Brief #1*, New York, IAVI.
IAVI (2006), *Imagine a World without AIDS: The History of the International AIDS Vaccine Initiative*, New York, IAVI.
IAVI (2007a), 'The International AIDS Vaccine Initiative 2006 Annual Progress Report', New York, IAVI.
IAVI (2007b), 'R&D Models: Lessons from Vaccine History', *Policy Research Working Paper*, New York, IAVI Public Policy Department.
Jack, A. (2005), 'Public-Private Partnerships: An antidote to neglected diseases', *Financial Times*, London, The Financial Times Limited.
Johnson, B. and Lundvall, B. A. (2002), 'National Systems of Innovation and Economic Development', *in* M. Muchie, P. Gammeltoft and B. A. Lundvall (eds.), *Putting Africa First: The Making of African Innovation Systems*, Aalborg, Aalborg University Press.
Jones, P. S. (2004), 'When 'development' devastates: donor discourses, access to HIV/AIDS treatment in Africa and rethinking the landscape of development', *Third World Quarterly*, 25, 2, 385-404.
Jørgensen, U. and Sørensen, O. (2002), 'Arenas of Development: A Space Populated by Actor-worlds, Artefacts, and Surprises', *in* K. H. Sørensen and R. Williams (eds.), *Shaping Technology, Guiding Policy: Concepts, Spaces and Tools*, UK/ Northampton, MA., Edward Elgar.
Kettler, H. E. and Marjanovic, S. (2004), 'Engaging biotechnology companies in the development of innovative solutions for diseases of poverty', *Nat Rev Drug Discov*, 3, 2, 171-6.
Kickbusch, I. and Quick, J. (1998), 'Partnerships for health in the Twentieth Century', *World Health Statistics Quarterly*, 51, 68-74.
Kiely, R. (1999), 'The Last Refuge of the Noble Savage? A Critical Assessment of Post-Development Theory', *The European Journal of Development Research*, 11, 1, 30-55.
Kirton, J., Schrecker, T. and Cooper, A. (2007), *Governing Global Health: Challenges, Response, Innovation*, Ashgate.

Knorr-Certina, K. and Cicourel, A. (1981), *Advances in Social Theory and Methodology: Toward and Integration of Micro- and Macro- Sociologies*, Boston, Routledge.
Kramer, M. (2000), 'Creating Markets for New Vaccines - Part 1: Rationale', *Working Paper # w7716*, Cambridge, Mass., NBER.
Labonte, R. and Spiegel, J. (2003), 'Setting global health research priorities', *British Medical Journal*, 326, 722-723.
Lansang, M. and Dennis, R. (2004), 'Building capacity in health research in the developing world', *Bull World Health Organ*, 82, 10, 764-9.
Latour, B. (2005), *Reassembling the social: an introduction to actor-network-theory*, Oxford, Oxford University Press.
Lee, K. (2003), *Health Impacts Globalization: Towards Global Governance*, Palgrave-MacMillan.
Lee, K., Buse, K. and Fustukian, S. (2002), *Health Policy in the Globalising World*, Oxford, Oxford University Press.
Lowell, B. L. and Findley, A. M. (2001), 'Migration of Highly Skilled Persons from Developing Countries: Impact and Policy Responses Synthesis Report', Geneva, ILO/DfID.
Lundvall, B. A. (1995), *National Systems of Innovation: towards a theory of innovation and interactive learning*, London, Pinter.
Lundvall, B. A., Muchie, M. and Gammeltoft, P. (2003), 'Introduction', *in* M. Muchie, P. Gammeltoft and B. A. Lundvall (eds.), *Putting Africa First: The Making of African Innovation Systems*, Aalborg, Aolborg University Press.
Mackintosh, M. and Koivusalo, M. (eds.) (2005), *Commercialisation of healthcare: Global and local dynamics and policy responses*, Palgrave, Basingstoke.
Mahoney, R. and Morel, C. M. (2006), 'A Global Health Innovation System (GHIS)', *Innovation Strategy Today*, 2, 1, 1-12.
Mahoney, R. T., Krattiger, A., Clemens, J. D. and Curtiss, R. I. (2007), 'The introduction of new vaccines into developing countries IV: Global Access Strategies', *Vaccine*, 25, 20, 4003-4011.
Martens, J. (2007), 'Multistakeholder Partnerships: Future Models of Multilateralism?' *Occasional Paper Series*, Berlin, Friedrich-Ebert Stiftung.
Martineau, T., Decker, K. and Bundred, P. (2004), '"Brain drain" of health professionals: from rhetoric to responsible action', *Health Policy*, 70, 1, 1-10.
Massey, B. (1998), 'The way we do things here: the culture of ethnography', *Ethnography and Education Conference*, Oxford University, Department of Educational Studies (OUDES).
McPake, B., Kumaranayake, L. and Normand, C. (2002), *Health Economics: an International Perspective*, London, Routledge.
Metcalfe, J. S. (1994), 'The Economics of Evolution and the Economics of Technology Policy', *Economic Journal*, 104, 931-944.
Metcalfe, J. S. (1998), *Evolutionary Economics and Creative Destruction*, London, Routledge.
Metcalfe, J. S., James, A. and Mina, A. (2005), 'Emergent innovation systems and the delivery of clinical services: The case of intra-ocular lenses', *Research Policy*, 34, 9, 1283-1304.
Milèn, A. (2001), 'What Do We Know about Capacity Building? An Overview of Existing Knowledge and Good Practice', Geneva, World Health Organisation.

Miller, G. and Dingwell, R. (1997), *Context and Method in Qualitative Research*, London, Sage.
Milstien, J. and Candries, B. (2000), *Economics of vaccine development and implementation: Changes over the past 20 years*, Geneva, World Health Organisation.
Mitchell-Weaver, C. and Manning, B. (1990), 'Public-private partnerships in Third World development', *The 20th Norma Wilkinson Memorial Lecture*, Reading, Reading University.
Moeran, B. (2005), *The Business of Ethnography: strategic exchanges, people and organisations*, Oxford, Berg.
Molyneux, D. H., Hotez, P. J. and Fenwick, A. (2005), '"Rapid-impact interventions": how a policy of integrated control for Africa's neglected tropical diseases could benefit the poor', *PLoS Med*, 2, 11, e336.
Moran, M. (2005), 'A breakthrough in R&D for neglected diseases: new ways to get the drugs we need', *PLoS Med*, 2, 9, e302.
Morel, C., Broun, D., Dangi, A., Elias, C., Gardner, C. A., Gupta, R. K., Haycock, J., Heher, T., Hotez, P., Kettler, H. E., Krattiger, A. F., Kreutz, F., Lee, K., Mashelkar, R. A., Mahoney, R., Min, H., Matlin, S. A., Mzimba, M., Oehler, J., Ridley, R. G., Senanayake, P., Singer, P. and Yun, M. (2005), 'Health Innovation in Developing Countries to Address Diseases of the Poor', *Innovation Strategy Today*, 1, 1, 1-15.
Morel, C. M., Acharya, T., Broun, D., Dangi, A., Elias, C., Ganguly, N. K., Gardner, C. A., Gupta, R. K., Haycock, J., Heher, A. D., Hotez, P. J., Kettler, H. E., Keusch, G. T., Krattiger, A. F., Kreutz, F. T., Lall, S., Lee, K., Mahoney, R., Martinez-Palomo, A., Mashelkar, R. A., Matlin, S. A., Mzimba, M., Oehler, J., Ridley, R. G., Senanayake, P., Singer, P. and Yun, M. (2005), 'Health innovation networks to help developing countries address neglected diseases', *Science*, 309, 5733, 401-4.
Morgan, P. (2003), 'Capacity Development and PPPs'.
Mosse, D. (1998), 'Process-oriented approaches to development practice and social research: An introduction', *in* D. Mosse, J. Farrington and A. Rew (eds.), *Development as Process: Concepts and methods for working with complexity*, London, Routledge.
Mosse, D. (2005), *Cultivating Development: An Ethnography of Aid Policy and Practice*, London, Pluto Press.
Mosse, D., Farrington, J. and Rew, A. (1998), *Development as process: Concepts and methods for working with complexity*, London, Routledge.
Mosse, D. and Lewis, D. (2005), *The Aid Effect: Giving and Governing in International Development*, London, Pluto Press.
Mosse, D. and Lewis, D. (2006a), *Development Brokers and Translators: The Ethnography of Aid and Agencies*, Bloomfield, CT, Kumarian Press.
Mosse, D. and Lewis, D. (2006b), 'Theoretical Approaches To Brokerage and Translation in Development', *in* D. Mosse and D. Lewis (eds.), *Development Brokers and Translators: The Ethnography of Aid and Agencies*, Bloomfield, CT, Kumarian Press.
Mrazek, M. F. and Mossialos, E. (2003), 'Stimulating pharmaceutical research and development for neglected diseases', *Health Policy*, 64, 1, 75-88.

Mugabe, J. (2005), 'Health Innovation Systems in Developing Countries: Towards a Global Strategy for Capacity Building', *Report to the Commission on Intellectual Property Rights, Innovation and Public Health*.
Müller, M. (2006), 'Discourses of postmodern epistemology: radical impetus lost?' *Progress in Development Studies*, 6, 1, 306-320.
Muraskin, W. (2002), 'The Last Years of the CVI and the Birth of the GAVI', *in* M. R. Reich (ed.), *PPPs for Public Health*, Boston, Ma., Harvard University Press.
Muraskin, W. (2004), 'GAVI: Is it a new model for effective public-private cooperation in International Public Health?' *Working Paper*, JLI.
Muraskin, W. (2005), *Crusade to Immunize the World's Children*, Global Biobusiness Book.
Narula, R. (2003), *Globalization and Technology*, Cambridge, Polity.
National Council for Science and Technology (2004), 'Guidelines for ethical conduct of biomedical research involving human subjects in Kenya', Nairobi, National Council for Science and Technology.
Nchinda, T. C. (2002), 'Research capacity strengthening in the South', *Soc Sci Med*, 54, 11, 1699-1711.
Nelson, N. and Wright, S. (1995), *Power and Participatory Development: Theory and Practice*, London, Intermediate Technology Publications.
Neufeld, V. and Johnson, N. (2001), 'Forging Links for Health Research: Perspectives of the Council on Health Research for Development', Ottawa, International Development Research Centre.
New Scientist (2006), 'Beating Malaria', *New Scientist*, 20, 12, 26-35.
Nishter, S. (2004), 'Public-Private Partnerships - A Global Call to Action', *Health Research Policy and Systems*.
Nissen, M. and Levitt, R. (2002), 'Dynamic Models of Knowledge-Flow Dynamics', *Centre for Integrated Facility Engineering Working Paper #76*, Stanford University.
Nonaka, I. and Takeuchi, H. (1995), *The knowledge-creating company: How Japanese companies create the dynamics of innovation*, Oxford, Oxford University Press.
North, D. (1990), 'Institutions and transaction-cost theory of exchange', *in* J. Alt and K. Shepsle (eds.), *Perspectives on positive political economy*, Cambridge, Cambridge University Press.
Nuyens, Y. (2005), *No Research without Development: a challenge for capacity strengthening*, Geneva, Global Forum for Health Research.
Nwaka, S. and Ridley, R. G. (2003), 'Virtual drug discovery and development for neglected diseases through public-private partnerships', *Nat Rev Drug Discov*, 2, 11, 919-28.
Ockwell, D. and Rydin, Y. (2006), 'Conflicting Discourses of Knowledge: understanding the policy adoption of pro-burning knowledge claims in Cape York Peninsula, Australia', *Environmental Politics*, 13, 3, 379-398.
Ong, A. and Collier, S. J. (2004), *Global Assemblages: Technology, Politics and Ethics as Anthropological Problems*, Oxford, Blackwell Publishing.
Oriogio, G. (2004), 'Measuring performance of interventions in capacity building – a stepping stone through the marshes', *A Lesson Note for the African Capacity Building Foundation*, Zimbabwe.
Pang, T. (2003), 'Setting global health research priorities: ethics should also guide global health research', *BMJ*, 326, 7403, 1399.

Pang, T., Pablos-Mendez, A. and Ijsselmuiden, C. (2004), 'From Bangkok to Mexico — towards a framework for turning knowledge into actions to improve health systems', *Bull World Health Organ*, 82, 10, 720-722.
Patton, M. Q. (1990), *Qualitative evaluation and research methods* (2nd Edition), Newbury Park, Ca., Sage.
Penrose, A. (2000), 'Partnership', *in* D. Robinson, T. Hewitt and J. Harriss (eds.), *Managing Development: Understanding Inter-Organizational Relationships*, California, Sage Publications.
Perks, H. (2004), 'Exploring Processes of Resource Exchange and Co-creation in Strategic Partnering for New Product Development', *International Journal of Innovation Management*, 8, 1, 37-61.
Peters, D. H. and Phillips, T. (2004), 'Mectizan Donation Program: evaluation of a public-private partnerships', *Trop Med Int Health*, 9, 4, A4-A15.
Peters, P. E. (2000), *Development Encounters: Sites of Participation and Knowledge*, Harvard Institute for International Development.
Petryna, A. (2005), 'Ethical variability: Drug development and the globalization of clinical trials', *American Ethnologist*, 32, 183-197.
Petryna, A., Lakoff, A. and Kleinman, A. (eds.) (2006), *Global Pharmaceuticals: Ethics, Markets, Practices*, Duke University Press, Durham, NC.
Pickard, M. (2007), 'Reflections on relationships: the nature of *partnership* according to five NGOs in southern Mexico', *Development in Practice*, 17, 4-5, 575-581.
Pieterse, J. N. (2001), *Development Theory: Deconstructions/ Reconstructions*, London, Sage.
Pigg, S. L. (1995), 'Acronyms and effacement: traditional medical practitioners (TMP) in international health development', *Soc Sci Med*, 41, 1, 47-68.
Pisano, G. (2006), 'Can Science Be a Business? Lessons from Biotech', *Harvard Business Review*, October 2006.
Polanyi, M. (1967), *The Tacit Dimension* New York, Anchor Books.
Powell, W. W. and Gordal, S. (2005), 'Networks of innovators', *in* J. Fagerberg, D. C. Mowery and R. R. Nelson (eds.), *The Oxford Handbook of Innovation*, Oxford, Oxford University Press.
Priddy, F. (2007), 'Challenges in conducting HIV vaccine trials: an IAVI perspective', *IAVI presentation for HIV Vaccine Awareness Day, May 18, 2007*.
Principe, A. and Tell, F. (2001), 'Inter-project learning: processes and outcomes of knowledge codification in project-based firms', *Research Policy*, 30, 9, 1373-1394.
Putman, R. D. (1993), *Making democracy work: Civil traditions in modern Italy*, Princeton, Princeton University Press.
Quintas, P. (2002), 'Implications of the diversion of knowledge for innovation in networks', *in* J. d. l. Mothe and A. N. Link (eds.), *Alliances, Networks and Partnerships in the Innovation Process*, Boston, MA, Klewer.
Rahnema, M. (1993), 'Participation', *in* W. Sachs (ed.), *The Development Dictionary: A Guide to Knowledge as Power*, London, Zed Books Ltd.
Rahnema, M. and Bawtree, V. (1997), *The Post-Development Reader*, London, Zed Books Ltd.
Ramiah, I. and Reich, M. R. (2006), 'Building effective public-private partnerships: experiences and lessons from the African Comprehensive HIV/AIDS Partnerships (ACHAP).' *Soc Sci Med*, 63, 2, 397-408.

Rangan, S., Van Wassenhove, L. and Samii, R. (2003), 'Constructive partnerships: When alliances between private firms and public actors can enable creative strategies', INSEAD.
Rapoport, H. (2002), 'Who is afraid of the brain drain? Human capital flight and growth in developing countries', *Policy Brief*, Stanford, Stanford Institute of Economic Policy Research.
Reich, M. R. (2002), *PPPs for Public Health*, Boston, MA., Harvard University Press.
Rice, T. (1998), *The Economics of health reconsidered*, Chicago, Health Administration Press.
Richter, J. (2004), 'Public-Private Partnerships for Health: A trend with no alternatives?' *Development*, 47, 2, 43-48.
Rico, A., Saltman, R. B. and Boerma, W. G. W. (2003), 'Organizational restructuring in European health systems: the role of primary care', *Social Policy and Administration*, 37, 6, 592-608.
Ridley, R. G. (2001), 'Putting the partnership into public-private partnerships', *Bull World Health Organ*, 79, 694.
Rifkin, S. (2003), 'Foundations in Health Policy Lecture', LSE (MSc. HPPF), London.
Ritchie, J. and Spencer, L. (1994), 'Qualitative data analysis for applied policy research', *in* A. Bryman and R. G. Burgess (eds.), *Analysing Qualitative Data*, London, Routledge.
Ritsatakis, A., Barnes, R., Dekker, E., Harrington, P., Kokko, S. and Makara, P. (eds.) (2000), *Exploring Health Policy Development in Europe*, World Health Organisation Regional Office for Europe, Copenhagen.
Roberts, M. J., Breitenstein, A. G. and Roberts, C. S. (2002), 'The ethics of PPPs', *in* M. R. Reich (ed.), *PPPs for Public Health*, Boston, MA., Harvard University Press.
Robson, C. (1993), *Real World Research: A Resource for Social Scientists and Practitioner-Researchers*, Oxford, Blackwell.
Rod, M. R. M. and Paliwoda, S. J. (2003), 'Multi-sector collaboration: a stakeholder perspective on a government, industry and university collaborative venture', *Science and Public Policy*, 30, 4, 273-284.
Rosenau, J. R. (1995), 'Governance in the Twenty-first Century', *Global Governance*, 1, Winter, 13-43.
Rosiello, A. and Smith, J. (2004), 'A Sociological Economy of HIV/AIDS Vaccine Partnerships in Africa and India', *Economic Sociology 2004*, Crete, Greece.
Sachs, W. (1992), *The Development Dictionary: A Guide to Knowledge as Power*, London, Zed Books.
Schacter, M. (2000), '"Capacity Building": A New Way of Doing Business for Development Assistance Organizations', *Policy Brief*, Institute on Governance Policy.
Scheirer, M. A. (1994), 'Designing and using process evaluation', *in* J. Wholey, H. Hatry and K. Newcomer (eds.), *Handbook of Practical Program Evaluation*, San Francisco, Jossey-Bass.
Schmookler, J. (1966), *Invention and Economic Growth*, Cambridge, MA., Harvard University Press.

Schofield, J. W. (1993), 'Increasing the generalisability of qualitative research', *in* M. Hammersley (ed.), *Social Research: Philosophy Politics and Practice*, London, Sage.
Schumpeter, J. A. (1934), *Theory of Economic Development: An enquiry into profits, capital, interest and the business cycle*, Cambridge, MA., Harvard University Press.
Scott, J. T. (2002), 'Absorptive Capacity and the Efficiency of Research Partnerships', *Working Paper*, Dartmouth College.
Segaar, D. (2004), 'Innovative Arrangements in International Health: The Implications of Private Involvement in Public Service Delivery', *in* Center for International Cooperation Draft (ed.).
Senge, P. (1990), *The Fifth Discipline: the Art and Practice of the Learning Organization*, New York, Doubleday.
Shiva, V. (1997), 'Western Science and Its Destruction of Local Knowledge', *in* M. Rahnema and V. Bawtree (eds.), *The Post-Development Reader*, London, Zed Books Ltd.
Singer, P. A. and Daar, A. S. (2001), 'Harnessing genomics and biotechnology to improve global health equity', *Science*, 294, 5540, 87-9.
Singleton, V. (1998), 'Stablizing instabilities: the role of the laboratory in the United Kingdom cervical screening programme', *in* M. Berg and A. Mol (eds.), *Differences in Medicine: Unravelling Practices, Techniques and Bodies*, London, Duke University Press.
Sismondo, S. (2004), *An Introduction to Science and Technology Studies*, Oxford, Blackwell.
Slater, D. and Tonkiss, F. (2001), *Market Society: Markets and Modern Social Theory*, Polity Press.
Smith, E., Brugha, R. and Zwi, A. (2001), 'Working with private sector providers for better health care, an introductory guide', London, Options
London School of Hygiene and Tropical Medicine.
Smith, M. (2001), 'Peter Senge and the learning organization '.
Smith, R., Woodward, D., Acharya, A., Beaglehole, R. and Drager, N. (2004), 'Communicable disease control: a 'Global Public Good' perspective', *Health Policy Plan*, 19, 5, 271-278.
Solnick, R., Ajayi, A., Cornejo, S., Hira, S., La Montagne, J. R. and Turnbull, J. (2003), 'Independent Evaluation of the International AIDS Vaccine Initiative'.
Star, S. L. and Griesemer, J. R. (1989), 'Institutional Ecology, 'Translations', and Boundary Objects: Amateurs and Professionals in Berkley's Museum of Vertebrate Zoology', *Social Studies of Science*, 19, 387-420.
Stiglitz, J. (1994), *Wither Socialism?*, Cambridge, MA., MIT Press.
Storey, A. (2000), 'Post-Development Theory: Romaticism and Pontius Pilate politics', *Development*, 43, 4, 40-46.
Szreter, S. and Woolcock, M. (2004), 'Health by Association? Social Capital, Social Theory and the Political Economy of Public Health', *International Journal of Epidemiology*, 33, 4, 650-657.
Tait, J. (2006), 'Systemic interactions in life science innovation', *Technology Analysis and Strategic Management*, 19, 3, 257-277.
Tait, J. and Lyall, C. (2007), 'Short Guide to Developing Interdisciplinary Research Proposals', *Briefing Note (Number 1) March 2007*, Edinburgh, ISSTI.

Taylor-Gooby, P. (2003), 'Introduction: Open Markets versus Welfare Citizenship: conflicting approaches to policy convergence in Europe', *Social Policy and Administration*, 37, 6, 539-554.
Taylor-Powell, E. and Rossing, B. (1996), 'Evaluating Collaborations: Challenges and Methods', American Evaluation Association.
Thornton, R. J. (1988), 'The Rhetoric of Ethnographic Holism', *Cultural Anthropology*, 3, 3, 285-303.
Tidd, J. (ed.) (2000), *From Knowledge Management to Strategic Competence: Measuring Technological, Market and Organizational Innovation*, Imperial College Press, London.
Tidd, J., Bessant, J. and Pavitt, K. (2005), 'Learning through alliances', *in* J. Tidd, J. Bessant and K. Pavitt (eds.), *Managing Innovation: Integrating Technological, Market and Organizational Change*, Chicester, Wiley.
Timmermans, S. (2005), 'From Autonomy to Accountability: the role of clinical practice guidelines in professional power ', *Perspectives in Biology and Medicine*, 48, 4, 490-501.
Trostle, J. A. (2000), 'Developing International Health Science Research: Measuring or Marginalizing Quality', *in* P. E. Peters (ed.), *Development Encounters: Sites of Participation and Knowledge*, Harvard Institute for International Development.
Tucker, V. (1999), 'The Myth of Development: A Critique of a Eurocentric Discourse', *in* R. Munck and D. O'Hearn (eds.), *Critical Development Theory: contributions to a new paradigm*, London, Zed Books Ltd.
UNAIDS (2004), 'Report on the Global AIDS Epidemic', Geneva, UNAIDS.
Unger, J.-P., De Paepe, P., Ghilbert, P., Soors, W. and Green, A. (2006), 'Disintegrated care: the Achilles heel of international health policies in low and middle income countries', *International Journal of Integrated Care*, 6, 18 September 2006.
Valentine, D. (2002), 'Ethnography'.
Vaughan, D. (2002), 'Signals and Interpretive Work: The Role of Culture in a Theory of Practical Action', *in* K. Cerulo (ed.), *Culture in Mind: Toward a Sociology of Culture and Cognition*, New York, Routledge.
Velho, L. (2006), 'Building a critical mass of researchers in the least developed countries: new challenges', *in* L. Box and R. Engelhard (eds.), *Science and Technology Policy for Development: Dialogues at the Interface*, London, Anthem Pess.
von Krogh, G., Ichijo, K. and Nonaka, I. (2000), *Enabling Knowledge Creation: How to Unlock the Mystery of Tacit Knowledge and Release the Power of Innovation*, New York, Oxford University Press.
Wagstaff, A., Claeson, M., Hecht, R. M., Gottret, P. and Fang, Q. (2006), 'Millennium Development Goals for Health: What Will It Take to Accelerate Progress?' *in* D. T. Jamison, J. G. Breman, A. R. Measham, G. Alleyne, M. Claeson, D. B. Evans, P. Jha, A. Mills and P. Musgrove (eds.), *Disease Control Priorities in Developing Countries* (2nd Edition), New York, Oxford University Press.
Walker, R. (1985), *Applied Qualitative Research*, Aldershot, Gower.
Walt, G. (1995), *Health Policy: an introduction to power and process*, London, Zed Books.
Walt, G. and Buse, K. (2000), 'Partnership and fragmentation in international health: threat or opportunity?' *Trop Med Int Health*, 5, 7, 467-71.

Walt, G. and Lush, L. (2001), 'Getting drugs to where they are needed: Global public private partnerships for neglected diseases', *Biotechnology and Development Monitor*, 2001, 46, 9-12.
Warhurst, C. (2001), 'Reviews', *Management Learning*, 32, 1, 148-151.
Weber, K. M. (2002), 'The Political Control of Large Socio-technical Systems: New Concepts and Empirical Applications from a Multi-disciplinary Perspective', *in* K. H. Sørensen and R. Williams (eds.), *Shaping Technology, Guiding Policy: Concepts, Spaces and Tools*, UK/ Northampton, MA, Edward Elgar.
Weijer, C. and LeBlanc, G. J. (2006), 'The balm of Gilead: Is the provision of treatment to those who seroconvert in HIV prevention trials a matter of moral obligation or moral negotiation?' *Journal of Law, Medicine and Ethics*, 34, 4, 793-808.
Wenger, E. (1998), *Communities of Practice: Learning, Meaning, and Identity*, Cambridge, Cambridge University Press.
WHO (2000), 'The World Health Report 2000 - Health Systems: Improving Performance', Geneva, World Health Organisation.
WHO (2004), 'Knowledge for Better Health Report', Geneva.
Widdus, R. (2003a), 'Private Sector Action for Health: Public-Private Partnerships', Presentation for the Initiative on Public Private Partnerships for Health.
Widdus, R. (2003b), 'Public-private partnerships for health require thoughtful evaluation', *Bull World Health Organ*, 81, 4, 235.
Widdus, R. and White, K. (2004), 'Combating Diseases Associated with Poverty: Financing Strategies for Product Development and the Potential Role of Public-Private Partnerships', Geneva, IPPPH.
Wildridge, V., Childs, S., Cawthra, L. and Madge, B. (2004), 'How to create successful partnerships - a review of the literature', *Health Information and Libraries Journal*, 21, 3-19.
Williamson, O. E. (1985), *Economic Institutions of Capitalism*, New York, Free London.
World Bank (1993), 'World Development Report: Investing in Health', New York, Oxford University Press.
Yamey, G. (2002), 'WHO in 2002: Faltering steps towards partnerships', *British Medical Journal*, 25, 23 November, 1236-1240.
Yin, R. K. (1994), *Case Study Research: Design and Methods*, Thousand Oaks, Ca., Sage.

Appendices

Appendix 1……..	Copy of IAVI's history timeline from the IAVI official history
Appendix 2……..	An IAVI organogram
Appendix 3……..	Interview documents: - Interview list - Interview guide
Appendix 4……..	List of documents sourced
Appendix 5……..	Example of a (ethnographic) map

Appendix 1

IAVI's historical timeline

This is taken directly from IAVI's "Imagine a World Without AIDS: A History of the International AIDS Vaccine Initiative" (2006)

1996	The International AIDS Vaccine Initiative (IAVI) is established to accelerate development of safe, effective AIDS vaccines for use throughout the world, supported by the Rockefeller and Alfred P. Sloan foundations, Fondation Mérieux, Until There's A Cure, the World Bank, and the Joint United Nations Programme on HIV/AIDS (UNAIDS). UNAIDS forms; more than 20 million people are living with HIV/AIDS worldwide. IAVI establishes its Scientific Advisory Committee to guide targeted vaccine development. IAVI launches an international campaign to create a Global HIV Vaccine Purchase Fund. Brazil is the first developing country to begin national ARV distribution. The *IAVI Report* is launched — the world's first AIDS vaccine research newsletter. IAVI consults with AIDS communities in Europe, North America, and developing countries to review the state of HIV vaccine R&D and seek advice on moving the field forward.
1997	Seth Berkley is named president and CEO of IAVI; Lee Smith becomes the first chairman of the board. U.S. President Clinton announces a ten-year goal to develop an AIDS vaccine and the creation of the Dale and Betty Bumpers Vaccine Research Center. Advocacy efforts gain momentum; IAVI works with about 70 organizations in 23 nations endorsing a "Call for Action." Leaders of the G8 identify AIDS vaccines as a top priority for the first time. The U.K.'s National AIDS Trust becomes IAVI's first formal NGO partner. IAVI awards its first three HIV vaccine R&D grants to research groups in Melbourne and Boston. IAVI launches its website: www.iavi.org.
1998	UNAIDS names IAVI as a collaborating center. The U.K. becomes IAVI's first government partner with a grant from the Department for International Development (DFID). IAVI unveils its first *Scientific Blueprint for AIDS Vaccine Development* as part of its strategic plan to speed HIV vaccine development with Vaccine Development Partnerships (VDPs) comprised of scientists in industrialized and developing countries. IAVI launches its first two VDPs, the first in global research to target clades A and C, the strains of HIV commonly found in Africa. Initial partnerships link the University of Nairobi/Kenya AIDS Vaccine Initiative (KAVI) with the U.K. Medical Research Council (MRC) and the American biotechnology company AlphaVax with the University of Cape Town. The Treatment Action Campaign (TAC) launches a grassroots movement in South Africa to push for access to treatment. Nearly 200 AIDS organizations sign on to IAVI's "Call to Action."
1999	The William H. Gates Foundation (later the Bill & Melinda Gates Foundation) awards IAVI $25 million — the

	Foundation's largest charitable AIDS gift at that time. The South African AIDS Vaccine Initiative (SAAVI) is founded to coordinate R&D and testing of HIV vaccines in South Africa. The Netherlands makes a commitment to funding IAVI. The world's first Phase III (efficacy) trials of an experimental AIDS vaccine (VaxGen's gp 120) begin in 60 sites around the world. Uganda hosts Africa's first AIDS vaccine trial.
2000	UNAIDS estimates over 30 million people are living with HIV globally. A third VDP with Targeted Genetics and Children's Research Institute of Columbus, Ohio, begins developing a recombinant adeno-associated virus vector (AAV)-based candidate. African researchers issue "The Nairobi Declaration: An African Appeal for an HIV Vaccine." UNAIDS publishes new guidelines on the ethical conduct of AIDS vaccine clinical trials. The U.S.-based Institute of Human Virology (IHV) and the Ugandan Ministry of Health investigate an affordable oral vaccine. Canada and Ireland offer multi-million dollar support to IAVI. At the XIII International AIDS conference in Durban, South Africa, IAVI issues *AIDS Vaccines for the World: Preparing Now to Assure Access*, outlining steps for simultaneous access to a successful vaccine in developing and developed countries. The first HIV vaccine specifically designed for Africa (DNA-MVA) receives approval for Phase I (safety) testing in the U.K. The U.S. Congress authorizes $16 million for IAVI via the U.S. Agency for International Development (USAID), the first U.S. contribution to IAVI.
2001	To galvanize support for IAVI's *Scientific Blueprint*, the Bill & Melinda Gates Foundation pledges a $100 million challenge grant — IAVI's largest single award to date. Yahoo! and Becton Dickinson (BD) become IAVI's first major corporate sponsors. Testing of the DNA-MVA candidate begins in Nairobi, Kenya, the country's first HIV vaccine trial. June 5th marks 20 years since the first AIDS cases were reported. IAVI launches its activities in India, including *Sankalp* newsletter. IAVI and Therion Biologics collaborate with the Indian Council of Medical Research (ICMR) to develop a multigenic MVA vaccine based on clade C, prevalent in Africa ,China, and India. The Canadian AIDS Society partners with IAVI to build greater commitment to speeding the search for an AIDS vaccine for the hardest-hit countries. The UN General Assembly's first Special Session on AIDS makes a commitment to "increase investment and accelerate research on the development of HIV vaccines… in highly affected regions…" Uganda and IAVI partner to test candidates, strengthen clinical trial infrastructure, and build the capacity of local scientists. IAVI opens its state-of-the-art Human Core Immunology Laboratory in London to facilitate coordination, quality control, and high-level training among its global partners. IAVI partners with Brazil's NGOs and National AIDS Program to keep vaccines on their agenda and further collaboration with other countries. IAVI's Access Project collaborates with WHO to publish a paper assessing the potential worldwide demand for HIV vaccines. With awards from Norway and Denmark, the number of donor countries supporting IAVI rises to seven. A vaccine preparedness program is launched with in-country partners to build and sustain an enabling environment in developing countries hosting IAVI's clinical trials.

2002	HIV becomes the leading cause of death worldwide within the 15-59 age group. UNAIDS reports women comprise about half of all adults living with HIV/AIDS. The World Economic Forum at Davos hosts a high-level meeting on AIDS vaccines. Berna Biotech of Switzerland joins the HIV vaccine development partnership to test an orally administered AIDS vaccine. The U.K/Kenya/IAVI partnership moves a DNA-MVA vaccine into Phase II trials in the U.K. The Swedish biotech firm Bioption AB teams with IAVI to develop an HIV vaccine using the Karolinska Institute's proprietary SFV alphavirus replicons technology. IAVI, the NIH Vaccine Research Center, and leading labs form the Neutralizing Antibody Consortium (NAC) — the first collaboration of its kind for making broadly neutralizing antibodies against HIV. IAVI and partners bring together parliamentarians and AIDS experts from nine countries to New Delhi, stimulating greater political commitment to fight AIDS in India. The Global Fund to Fight AIDS, Tuberculosis and Malaria is established. At the XIV International AIDS Conference in Barcelona, IAVI outlines its new R&D agenda to expand the number of candidate HIV vaccines in human efficacy trials. IAVI opens regional offices in Amsterdam and New Delhi. A web-based laboratory inventory management system (LIMS) is implemented at the Core Lab to track specimens from IAVI's global trial sites. IAVI initiates new laboratory centers of excellence to support future vaccine trials in Pune, India, and at the Uganda Virus Research Institute (UVRI) in Entebbe. A second Indian laboratory later opens in Chennai.
2003	Indian President A.P.J. Abdul Kalam sets AIDS vaccines as a national goal and endorses IAVI's work. The U.S. President's Emergency Plan for AIDS Relief, a five-year, $15 billion program, is announced. WHO unveils its "3 by 5" Initiative to bring treatment to 3 million people by 2005. The DNA-MVA vaccine enters Phase I trials in Uganda through IAVI partners at the UVRI. IAVI receives its first European Union funding for vaccine preparedness in East Africa. Sweden also donates. VaxGen Inc. announces disappointing results for its candidate, AIDSVAX. Although safe, it did not prove effective. IAVI's Nairobi, Kenya, regional office opens to support activities in East Africa. *VAX*, a monthly bulletin about AIDS vaccine research, clinical trials, and associated subjects, is launched. South Africa approves its first HIV vaccine trials, including one sponsored by IAVI. IAVI begins its first HIV vaccine trial in the U.S. with the Aaron Diamond AIDS Research Center (ADARC) using a candidate based on clade C. Targeted Genetics, Columbus Children's Research Institute, and IAVI begin human trials of a singleshot vaccine candidate (tgAAC09) in Belgium.
2004	IAVI halts the DNA-MVA candidate after Phase II clinical tests fail to achieve predetermined criteria to advance to Phase III; the SFV replicon candidate fails to go to Phase I. The NIH Vaccine Research Center announces the test of DNA + Adenovirus-5 candidate at IAVI sponsored sites in East Africa. The G8 again endorses the search for a vaccine, calling for creation of the Global HIV Vaccine Enterprise. The U.S. National Institute of Allergy and Infectious Diseases (NIAID) establishes the Center for HIV-AIDS Vaccine Immunology (CHAVI) — a consortium of universities and academic medical centers working in HIV vaccine development and design. IAVI expands its programs to mobilize public support for research, incentives for industry, and assistance to developing countries to test, license, and plan for affordable distribution. The IAVI Core Laboratory in London becomes the world's first lab to receive full Good Clinical Laboratory Practice (GCLP) accreditation. IAVI's *Scientific Blueprint 2004* calls for doubling current spending on AIDS vaccine development (then at $650 million).

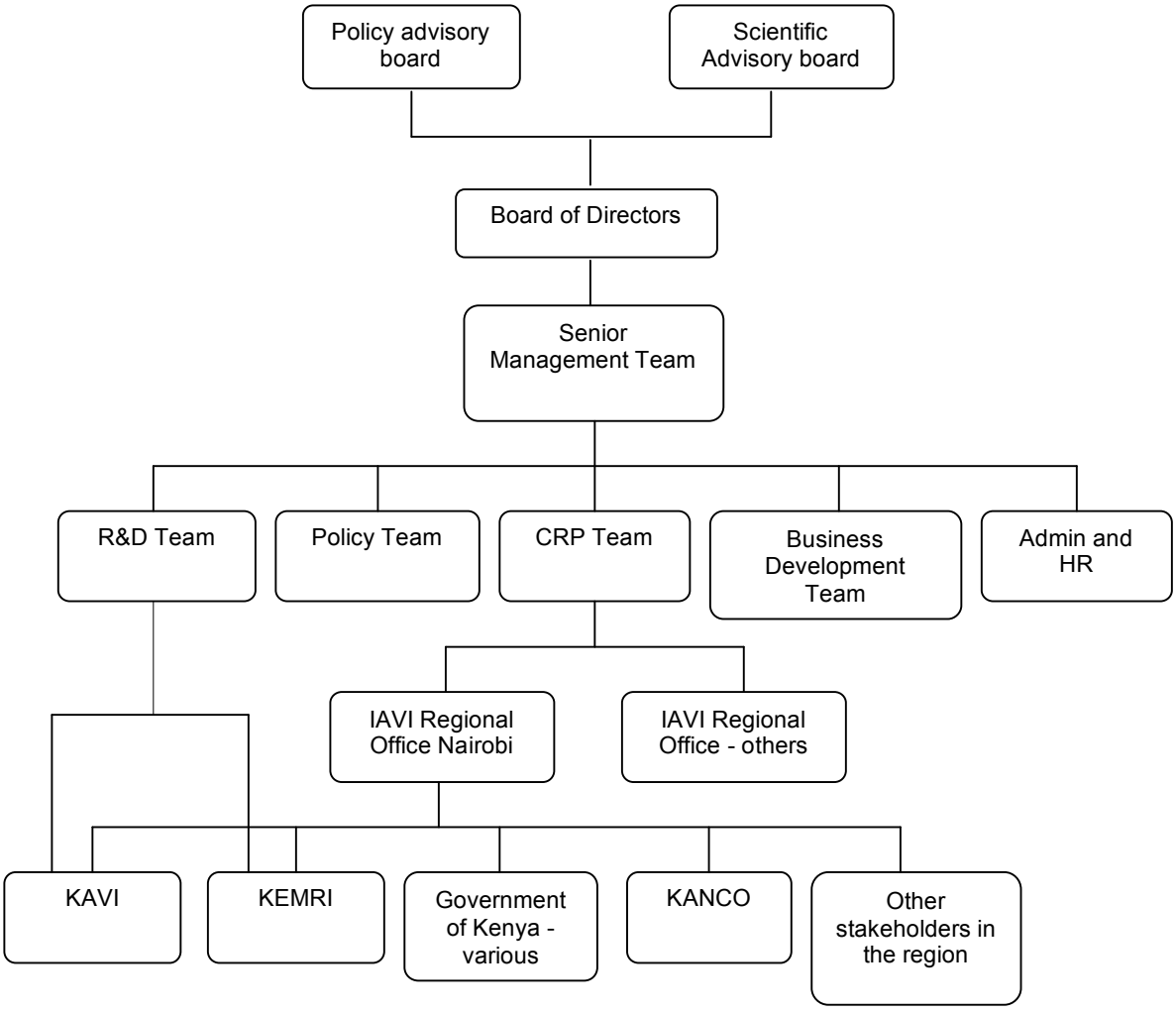
	To date, IAVI has sponsored testing of five vaccine candidates in 11 countries; 30 candidates are in clinical trials in 19 countries. IAVI helps KAVI begin epidemiological studies to examine HIV prevalence in Kangemi, Nairobi. The Dutch biotech firm Crucell N.V. grants IAVI exclusive license to use its AdVac® adenovirus vectors technology to develop an AIDS vaccine. IAVI launches the Live Attenuated Consortium (LAC) to accelerate vaccine candidates based on the model of SIV in non-human primates.
2005	UNAIDS estimates 38.6 million people are living with AIDS globally. IAVI conducts its first vaccine preparedness workshop in China. The Neutralizing Antibody Consortium (NAC) solves the crystal structure of monoclonal antibody E10. Uganda's President Yoweri Museveni calls on the G8 to provide greater support for AIDS vaccine R&D and endorses IAVI's work. IAVI's India partnership begins Phase I trials of a preventive vaccine (tgAAC09) in Pune, India. The Basque Autonomous Government funds a new vaccine trial center in Chennai, India. The Bill & Melinda Gates Foundation and NIH pledge $660 million over five years to support partners of the Global HIV Vaccine Enterprise. In New York, IAVI opens its first non-profit applied research, industrial-style AIDS Vaccine Development Laboratory. *Computerworld* awards IAVI its Medal of Achievement for innovative IT infrastructure. IAVI partners with GlaxoSmithKline Biologicals to develop AIDS vaccines based on chimpanzee adenoviruses. The IAVI/Targeted Genetics partnership launches the first Phase II vaccine tgAAC09 trials at the first of three sites in South Africa. Brazil, India, and South Africa ask IAVI to organize a meeting in Cape Town to develop trilateral AIDS vaccine projects. Emory University's Project San Francisco, IAVI, and NIH launch Rwanda's first vaccine trial. IAVI's policy paper, "Putting It Together: AIDS and the Millennium Development Goals (MDGs)," is published for the UN. IAVI's first estimates of the potential impact of an AIDS vaccine become standard reference.
2006	Testing of the IAVI/Targeted Genetics tgAAC09 candidate expands to Uganda and Zambia. KAVI, IAVI, and the NIH's Vaccine Research Center launch trials of a VRC-designed candidate in Nairobi, Kenya. India's second AIDS vaccine trial is launched in Chennai through the ICMR, the National AIDS Control Organization, and IAVI. IAVI grants Beth Israel Deaconess Medical Center a license to use AdVac®, an adenovirus-based vaccine production technology. The Zambia Emory HIV Research Project, IAVI, and Targeted Genetics initiate its first HIV vaccine trial in Zambia. The UVRI/IAVI Entebbe lab is fully GCLP-accredited; the KAVI/Kangemi field lab in Nairobi follows. The UN General Assembly Special Session on AIDS (UNGASS+5) backs vaccines. G8 Summit leaders endorse the Global AIDS Vaccine Enterprise. The Scripps Research Institute and IAVI unveil a robot that rapidly determines the molecular crystal structure of the HIV envelope. The Bill & Melinda Gates Foundation awards $287 million to support the Collaboration for AIDS Vaccine Discovery (CAVD) comprised of 16 HIV vaccine development centers. IAVI receives $23.7 million from the Bill & Melinda Gates Foundation and $9.2 million together with Duke University and NIH.

	IAVI signs a five-year, $155 million cooperative agreement with USAID. IAVI launches the *AIDS Vaccine Blueprint 2006* at the XV International AIDS Conference in Toronto, setting forth new initiatives for overcoming AIDS vaccine challenges. IAVI opens its southern Africa regional office in Johannesburg, South Africa.

Appendix 2

An IAVI Organogram

Below I have outlined my (graphical) interpretation of IAVI's organisational structure based on the discussions I have had and the documents I have accessed during my fieldwork. IAVI's official organogram is not publicly available. This chart is focused on the line of organisation into Kenya within IAVI and so does not cover, for example, IAVI's activities in other countries or with donors.



Appendix 3

Interview documents

3.1 Interview list

Institution	Position	#	Transcript
IAVI	Regional Representative	1	taped
	Senior Director Medical Affairs	1	taped
	Policy	2	taped
	Community Mobilisation	1	taped
	Clinical Trials	1	taped
KAVI Kenyatta National Hospital	Head of Unit	1	taped
	Principal Investigators	2	taped
	Doctors	2	taped
	Head of Lab	1	taped
	Lab technicians	2	taped
	Nurse Counsellors	2	taped
	Community Mobilisers	2	taped
	Peer Leaders	2	taped
	CAB member	1	taped
	Pharmacist	1	taped
	Data manager	1	notes
KAVI Kangemi	Trial Physician	2	notes, taped
	Lab technician	1	notes
	Nurse Counsellors	1	taped
	Peer Leader & CAB member	1	taped
Kilifi	Principal Investigator	1	taped
	Doctors	3	taped x 2, emailed
	Lab technicians	2	taped, notes
	Nurse Counsellors	5	taped
	Community Mobilisers	2	notes
	Head of Mtwapa clinic	1	taped
	Administrator	1	taped
	Data manager	2	taped, notes
KEMRI Kilifi	Head of CGMRC	1	emailed
	Doctors	1	notes

KEMRI	Assistant Director	1	notes
District Medical Staff	Kenyatta National Hospital/University of Nairobi Representative	1	taped
	Kangemi Clinic Nurse in Charge	1	notes
	Kilifi Hospital Director	1	taped
	Kilifi District Medical Officer	1	notes
	Coast Province Provincial Medical Officer	1	notes
	Coast Province Pathologist/ Senior Research Scientist	1	notes
Ministry of Health	MOH, Research and Standards Unit Head	1	notes
	Secretary HIV vaccine sub-committee	1	notes
World Health Organisation	A Representative	1	notes
Kenya AIDS NGO Coalition	A Representative	1	taped
National AIDS Control Council	A Representative	1	taped
National Council of Science and Technology	A Representative	1	taped
Other vaccine stakeholders	Representatives of CDC & UNAIDS	2	notes
	TOTAL	**62**	

3.2 Interview guide

Preliminary explanation

- I am conducting a case study of IAVI to:
    a. Identify possible linkages between collaboration and knowledge capacity building
    b. To examine the extent knowledge and information transfers impact the links between those involved in innovation and those involved in health service provision at country level in Kenya

- To do this I am conducting discussions with a number of organisations who are involved in IAVI including your organisation.

- I am interested to know about:
    a. The organisation and its role in the PPP
    b. How the partnership works at the present time including how and when information, knowledge and learning are transferred and how capacity building activities take place
    c. How or if your work as an organisation relates to innovation and to health service provision

- The interview should take approximately one hour.

- Please ask at any time if you would like clarification on any aspect of the interview.

- The information collected in the interviews could be used in the following ways:
    a. Unlinked to the informant – pooled with other informants and attributed to a named group of actors e.g. donors, policy makers
    b. Unlinked to the informant – used to express the anonymous views of an individual informant
    c. To document the views of a particular interviewee.

- Do you have any comments on these uses for the information? How would you like me to use the information?

- Unless you agree, I will not attribute anything in the report to you personally.

- You can go “off the record” and “on the record” at any point during the interview.

- You can terminate the interview at any point.

- The information I receive from these interviews will go towards my PhD thesis. I will also try to disseminate the findings further e.g. in a journal. Copies of the case report will be sent to all those involved in the study and feedback sessions will be held during my PhD.

- Any ideas that you have regarding the research would be very helpful – issues that I do not raise in the interview, areas of study I haven’t mentioned yet, etc. Please mention them at any point.

Please sign that you:		Date:
a. Consent to being interviewed:		
b. Consent to being taped:		
Print Name:		
Signature of interviewer:		

Collaboration and knowledge capacity – Interview Guide

A. Ice Breakers/ Background

1. Can you tell me a little about the organisation and its role within the IAVI partnership?
2. What is your role in this organisation?
3. Now I'd like you to tell me how the partnership started?
   Probes: When did it start?
   How and by who?

B. The Current Situation

4. Let's look at what's happening now. The company has been involved for X years now – how has the partnership worked during this time?
   Probes: Who does the company work with on a regular basis?
   What activities are undertaken?
   What has been successful and what has been unsuccessful?
5. Overall, to date, how successful do you think the partnership has been?
6. How would you describe IAVI?
   Probes: Would you call it a collaborative arrangement? Is it a PPP?
   How would you define a 'PPP'?

C. Capacity building

C1. Individual Level (to be answered by all):

7. What do you understand the term 'capacity building' to mean?
8. Do you feel that the partnership provides capacity building opportunities, as you understand the term?
   Probes: What are these?
   How would you describe capacity building activities that you have participated in?
   What training opportunities have you had? Would you want them?
9. Are such opportunities important/ necessary?
10. If you've had training opportunities, have they helped you in your ability to work?
11. Do you have any other comments on capacity building opportunities?

C2. Institutional Level (to be answered by programme managers):

12. Describe the staff complement in your organisation?
    Probes: How many staff and in what areas?
    What are their academic backgrounds?
    (If this is not known I will need to ask individuals when interviewed)
13. Does the organisation engage in capacity building activities, as you understand the term?
    Probes: What are these and why are they seen as important?
    How often take place?
    If not, why not?
14. What are the institutional level problems that the organisation encounters?
    Probes: Do capacity building activities ever not occur as intended? Why?
    Do you ever encounter resistance to capacity building?
    What would you like to see improve?
15. What impact could/ does/ has capacity building had on your operations?
    Probes: Has/ could/ does capacity building activities helped your organisation in its activities?
    In what ways?
    Or has it hindered activities?
    Has it strengthened the collaboration that occurs? If so, where?

C3. Macro Level (to be answered by all managers and reps of donors/ ministries):

16. Do capacity building activities, as you understand the term, improve the work environment of IAVI?
17. How does it do this?
18. What impact has it had to date and what impact will it have in the future?
19. (Do you think capacity building activities are useful at a policy level as well at the scientific and technical level?)

D. Knowledge, Information and Learning

D1. Individual level (to be answered by all):

20. What do you understand the terms 'knowledge', 'learning' and 'information' to mean/ to refer to?
21. Who do you interact with, how and why on daily, weekly, monthly basis?
22. What information and to who is it passed on to?
23. What information is then used and how?
24. What information is not received that might be useful?
25. What information is received but isn't useful?
26. Why information is important?
27. What knowledge is important and when do you receive it?
28. What learning is important and when do you receive it?

D2. Institutional level (to be answered by programme managers):

29. What are the institutional arrangements of the partnership and how have they worked to date?
    Probes: How is the partnership supposed to function? Why?
30. What are the governance and decision making processes within the partnership?
31. Is there any regular codification of information or information dissemination activities? What are they?

D3. Macro level (to be answered by all managers and reps of donors/ ministries):

32. What support does the partnership receive from government, donors and community?
33. How support is manifested and used?
34. How is knowledge passed to government, donors and community by the partnership and what is its impact?

E. Innovation and health

35. Would you say your organisation is involved in innovation or health service provision activities, or maybe both? Why?
36. What interaction does your organisation have with the other [innovation/ health] activities? What form does this take?
37. Do you think there needs to be more interaction between innovation and health service provision activities? Why?
38. Would you say the activities you are involved in fit into a certain 'system' of work? Which and why?

F. Other Comments

39. How have you as an individual viewed the partnership?
    Probes: What have you gained from being in the partnership?
    Why did you become involved – was it a specific choice?
    Have you benefited in different ways than the organisation as a whole?
    What are your personal views regarding the partnership?
40. Based on what we have just discussed is there anything you would like to ask me or tell me?

Appendix 4

List of documents sourced

IAVI documents

1. R&D Models: Lessons from Vaccine History – IAVI Policy research working paper # 14 (2007)
2. A review of European Commission funding for HIV/AIDS, Tuberculosis and Malaria Health Technology R&D – IAVI policy research working paper # 9 (2006)
3. AIDS Vaccine Blueprint 2006: Actions to Strengthen Global Research and Development – IAVI (2006)
4. AIDS Vaccine Blueprint
5. Imagine a world without AIDS: A History of IAVI – IAVI (2006)
6. IAVI Annual Progress Reports 2001 - 2006
7. IAVI Strategic Plan 2005 – 2007
8. IAVI's Expanded Community Outreach Programme overview
9. AIDS Vaccine literacy toolkit – IAVI (2005)
10. IAVI VAX Reports

Government of Kenya documents

11. Guidelines for ethical conduct of biomedical research involving human subjects in Kenya – National Council of Science and Technology, Government of Kenya (2004)
12. Kenya National Guidelines for Research and Development of HIV/AIDS Vaccines – Ministry of Health, Government of Kenya (2005)
13. Kenya National HIV/AIDS Strategic Plan: 2005 – 2010 – National AIDS Control Council, Government of Kenya (2005)

Research organisation related documents

14. KAVI Technical Trial Working Group meeting minutes and agenda March 2006
15. KAVI Organogram and staff list
16. KEMRI-CGMRC IAVI Project organisational breakdown and staff list

Other documents

17. Adding it all up: Funding for HIV Vaccine and Microbicide Development, 2000 to 2005 – HIV Vaccines and Microbicides Resource Tracking Working Group (2006)
18. Minutes and agenda for KNH CAB meeting February and May 2006
19. IAVI Bellagio meeting report (2006)
20. AIDS Vaccine trials set to start – Daily Nation newspaper article (February 2006)
21. Volunteers overwhelm AIDS vaccine team – The Standard newspaper article (May 2006)
22. Vaccine Day marked – Daily Nation newspaper article (May 2006)
23. Declaration of commitment on HIV/AIDS – UNGASS (2001)
24. Political Declaration on HIV/AIDS – UNGASS (2006)

Appendix 5

Map example